A randomised control trial comparing occupational therapy interventions that aim to improve developmental outcomes for HIV-positive children (aged 6 months – 5 years) on ART

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Declaration

I, Robyn Meissner, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Abstract

Background

Antiretroviral treatment (ART) has reduced the mortality rate of HIV-positive children significantly, and is known to prevent the development and progression of HIV encephalopathy. However, even with ART, perinatal HIV infection places HIV-infected children at increased risk for encephalopathy and associated developmental delays. Research is lacking in the extent of developmental delay on children established on ART, along with evidence-based occupational therapy interventions to treat these developmental delays. A play-informed, caregiver-implemented, home-based group occupational therapy intervention (PICIHBI) presents one possible service delivery option to be explored.

Aim

To determine whether children attending an experimental group (PICIHBI) versus children attending a control group (conventional, individual occupational therapy intervention) would present similar results in their total developmental quotient – on the Griffiths Mental Developmental Scales (GMDS) and Paediatric Functional Independence Measure (WeeFIM).

Methods

A randomised control trial, which was pragmatic in nature and single-blinded, was used. The research population was all HIV-positive children, pre-formal school-going aged (6 months – 5 years), on ART attending the Groote Schuur Hospital paediatric HIV clinic at the time of the study. Caregiver and child dyads were randomly assigned to either the experimental or control group, and attended a monthly occupational therapy session. Differences in the GMDS and WeeFIM scores of each child after 5 and 10 months' intervention were compared.

Results

Inter-rater reliability was established among the five researchers performing the GMDS before baseline assessments. Forty-two participants were recruited from a possible population of 72 participants and 39 participated in the baseline assessment. Twenty-eight participants completed mid and post assessments, 15 in the experimental PICIHBI group and 13 in the control group (90% power). Baseline averages on the GMDS showed the

participants scoring at a borderline mental retardation level, with better performance in the locomotor and personal-social subscales, before interventions. Both groups had an average attendance of 5 sessions. Post-interventions, average total GMDS and WeeFIM scores between the two groups revealed similar scores within the predetermined non-inferiority margin and no significant differences at any time point.

Conclusion

In conclusion, the low baseline scores confirm the need for occupational therapy intervention in pre-formal school-going HIV-positive children on ART. The PICIHBI intervention demonstrates a non-inferior impact in child development in this group compared to conventional, individual occupational therapy intervention. PICIHBI thus has potential for impacting occupational therapy practice in this field by providing an alternative equivalent treatment with increased reach.

Trial registered with South African Department of Health (2013 RP 185). Funded by South African Medical Research Council, National Research Foundation and DG Murray Trust.

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List of Abbreviations

ADLs	Activities of daily living
ARICD	Association for Research in Infant and Child Development
ART	Antiretroviral treatment
ARV	Antiretroviral
ATICC	AIDS Training Information and Counselling Centre
CAPS	Curriculum and assessment policy statements
CI	Confidence interval
CP	Cerebral Palsy
CONSORT	Consolidated Standards of Reporting Trials
DNA	Did not arrive
ECD	Early childhood development
FASD	Foetal Alcohol Spectrum Disorder
FIM	Functional Independence Measure
GMDS	Griffith Mental Development Scales (both the GMDS 0-2 and the GMDS-ER)
GMDS 0-2	Griffiths Mental Development Scales (from birth – 2years old) (ARICD, 1996)
GMDS-ER	Griffiths Mental Development Scales – extended and revised (ARICD, 2006)
GSH	Groote Schuur Hospital
HIV	Human Immunodeficiency Virus
HIVE	HIV Encephalopathy
Kidzpositive	Kidzpositive Family Fund
LTFU	Lost to follow-up
NGO	Non-governmental organisation
PICIHBI	Play-informed caregiver-implemented home-based intervention
PMTCT	Prevention of mother to child transmission

RCCH	Red Cross War Memorial Children's Hospital
SD	Standard deviation
TFO	Transferred out to another clinic
UCT	University of Cape Town
USDMR	Uniform Data System for Medical Rehabilitation
WeeFIM	Paediatric Functional Independence Measure
WHO	World Health Organisation

Definition of Terms

Antiretroviral treatment (ART): a combination of three antiretroviral (ARV) drugs used to treat people who are infected with the human immunodeficiency virus (HIV). The three drugs block and prevent the multiplication of the HIV at different points of the virus replication process. (Woods & Eley, 2010)

Development: Development in the context of human beings is defined as the "sequential changes in function that occur with maturation of the individual" (Law *et al.*, 2005: 54). In this research project, the term development encompasses the performance of the child aged between 6 months and 5 years in the following developmental areas: eye-hand coordination, locomotor, personal- social, language, performance, and practical reasoning. These areas are defined below:

Dosage: the amount of intervention sessions attended.

Eye-hand coordination: "the child's fine motor skills, manual dexterity and visual monitoring skills (ARICD, 2006: 3).

First-line treatment: the routinely given combination of three ARV drugs determined by the National guidelines (National Department of Health South Africa, 2015). (Woods & Eley, 2010)

Language: "the child's receptive and expressive language." (ARICD, 2006: 3)

Locomotor: "the child's gross motor skills including his (*sic*) ability to balance and coordinate and control movements" (ARICD, 2006: 3).

Low socioeconomic status: in the current study, participants were determined to be of low socioeconomic status if their income was eligible to receive a child support grant. The South African Social Security Agency stipulates to receive a child support grant: the caregiver (single) must have an annual income of less than R42 000 (or R3 500 per month) or combined (if married) annual income of R84 000 (or R7 000 per month). The amount of below R3 500 per month was considered eligible and used for the current study as marital status of the caregiver was unknown.

Performance: "the child's visuospatial skills including speed of working and precision." (ARICD, 2006: 3)

Personal-social: "the child's proficiency in the activities of daily living, his (*sic*) level of independence and his (*sic*) ability to interact with other children." (ARICD, 2006: 3). This is also referred to as **self-care**: activities undertaken to take care of one's body,

performed in socially appropriate ways, which children need to learn as preparation for independent living as adults (Shepherd, 2005; American Occupational Therapy Association, 2008).

Practical Reasoning: "the child's ability to solve practical problems, his (*sic*) understanding of basic mathematical concepts and questions about moral and sequential issues." (ARICD, 2006: 3)

Second-line treatment: if a patient fails to respond to first-line treatment, they are changed to a new combination of ARV drugs known as second-line treatment. (Woods & Eley, 2010)

Viral load: is blood test to check the amount of HIV cells in the blood. The viral load is considered to be supressed if the result is less than 400 RNA copies (HIV cells) per millilitre of blood. If it is above this level, the viral load is unsuppressed.

Chapter 1: INTRODUCTION, RATIONALE AND LITERATURE REVIEW

Introduction[1]

The early years in a child's life are seen as the most important from a developmental perspective as large amounts of development and pruning happen during these years in brain cells and neural pathways (Zigler, 2000; Grantham-McGregor & Cheung, 2007). Positive and progressive development in the early childhood years "provides the building blocks for a lifetime of success in many domains of life, including economic, social and physical well-being" (Irwin, Siddiqi & Hertzman, 2007: 19). If this period of opportunity is not taken advantage of – "it becomes increasingly difficult, in terms of both time and resources, to create a successful life-course" (Irwin, Siddiqi & Hertzman, 2007: 15). Child development is a key occupation and an integral focus in the paediatric domain of occupational therapy practice (Law *et al.*, 2005).

Occupational therapists view child development as "the process of maturation through which an infant finally reaches adulthood and attains a repertoire of adult skills" (Hagedorn, 1995: 45). Hagedorn continues to describe development as being "concerned with turning potential into useable ability, in creating the building blocks of skills which can be used and established as part of a person's repertoire" (Hagedorn, 1995: 46). Occupational therapists focus on how development evolves into functional performance of occupations (Kramer & Hinojosa, 2010). Developmental skills concentrated in the early childhood years are those related to gross and fine motor aspects (locomotor and eye-hand coordination) as well as

[1]Literature for this research dissertation and indeed, for the study itself was gathered by using combinations of the following search terms (with the use of Boolean Operators): child development, HIV, Griffiths Mental Development Scales, occupational therapy, and early childhood development on the following database platforms: EBSCOHost and Google Scholar and the following databases: Academic Search Premier, Medline, CINAHL, PsycINFO, PsycARTICLES, PsycTESTS, Health Source – Consumer Edition, Health Source: Nursing/Academic Edition and the Cochrane Library. A focus on publications in the last 10 years (2004 – present) was used as a filter. Many of the articles' citations uncovered additional research that did not appear in initial searches. The search terms were also employed to scan the UCT library ALEPH catalogue. Additional sources were gathered from recommendations from supervisors and colleagues. The Cochrane Library yielded no relevant Cochrane reviews on the above-mentioned terms. Only one Cochrane review was found describing home-based childhood interventions in socially disadvantaged families. Additionally, email alerts were set up on EBSCOHost, Google Scholar and PubMed with the above mentioned search terms. Relevant grey literature was searched for online, under the relevant South African government departments.

independence in activities of daily living (ADLs) and social interactions (personal-social) (Case-Smith, 2005). These skills are vital to the child being able to perform activities within their play, social and learning occupations (Law *et al.*, 2005; Jacklin & Cockcraft, 2013).

Problem Statement

For many children living in South Africa, development is jeopardised for a number of reasons such as poverty, malnutrition, caregiver factors, and education access and quality (Berry *et al.*, 2013). Critically, Human Immunodeficiency Virus (HIV) presents an additional burden to the already compromised development of these children (Burns, Hernandez-Reif & Jessee, 2008; Berry *et al.*, 2013). HIV is well documented to have a negative impact on developmental skills (gross motor, fine motor, cognitive, language, behavioural, emotional and social development) of children who are infected (Foster *et al.*, 2006; Abubakar *et al.*, 2008; Burns, Hernandez-Reif & Jessee, 2008; Richter *et al.*, 2009; Sherr, Mueller & Varrall, 2009; Smith, Adnams & Eley, 2010; Brahmbhatt *et al.*, 2014). This is a significant problem as the 2012 South African statistics state the prevalence of children, 0-4 years old with HIV, as 1.7 % of this age-group population (as estimated by Shisana *et al.*, 2014).

Antiretroviral treatment (ART), a medical drug intervention, has reduced the mortality rate of HIV-positive children significantly (Sherr, 2005; Abubakar *et al.*, 2008; Burns, Hernandez-Reif & Jessee, 2008; World Health Organization, 2010; Maartens, Celum & Lewin, 2014). ART is known to curb the development of and progression of HIV encephalopathy (HIVE) (Foster *et al.*, 2006; Van Rie *et al.*, 2007; Sherr, Mueller & Varrall, 2009; Hilburn, Potterton & Stewart, 2010; Donald *et al.*, 2014). HIVE is the most common central nervous system (CNS) complication in HIV-positive children and is the result of early invasion of the CNS by HIV (including the foetal or infant brain) (Donald *et al.*, 2015). HIVE is considered a stage 4 criteria[2] of HIV and an AIDS defining illness (World Health Organization, 2007; National Department of Health South Africa, 2015) and presents as delay in developmental milestones or loss of intellectual ability; impaired brain growth; and motor deficits, definitively diagnosed through neuroimaging (World Health Organization, 2007). In general, in medical services in the Cape Town area, HIVE is often unrecognised due to various contextual elements and a lack of specialized neurology services (Donald *et al.*, 2015). As a result, many cases of HIVE are undiagnosed (Donald *et al.*, 2015), yet there are still children

[2] The WHO has divided the progression of HIV infection into four clinical stages as the illness becomes more severe (World Health Organization, 2007). The stages are used to monitor the clinical progression as well as indicate when to start HAART. The South African National Department of Health follows these stages in their HIV treatment guidelines(2015).

living with the characteristics and resulting difficulties – including cognitive, neurological, behavioural and scholastic impairments (Van Rie *et al.*, 2007).

Even with the provision of ART, perinatal HIV infection continues to place HIV infected children at increased risk for encephalopathy and associated developmental delays (Burns, Hernandez-Reif & Jessee, 2008; Puthanakit *et al.*, 2010; Laughton *et al.*, 2012, 2013; Whitehead, Potterton & Coovadia, 2013; Brahmbhatt *et al.*, 2014; Donald *et al.*, 2015). Foster, Biggs, Melvin, Walters, Tudor-Williams, and Lyall (2006) and Ferguson and Jelsma (2009) found that motor impairments persisted after starting ART (tested both under 6 months of treatment and over 6 months of treatment) – indicating neurological damage caused by HIV is irreversible. Other studies have however shown that the earlier commencement of a child on ART is an important factor in curbing and eliminating the risk of sequential neurodevelopmental problems (Smith, Adnams & Eley, 2010; Laughton *et al.*, 2012; Brahmbhatt *et al.*, 2014). A recent South African study indicated that, even though ART was initiated in infants between 8 and 12 weeks of age, more than half of the infants (62%) already had advanced HIV disease (Innes *et al.*, 2014), which could also result in neurological involvement.

South Africa's ART coverage of children aged 0-14 years old living with HIV stands at only 45.1 % (Shisana *et al.*, 2014). ART is an important component in the prevention of mother to child transmission programme (PMTCT). This programme has been employed throughout South Africa to decrease the number of infected children as a result of vertical transmission of the virus (National Department of Health South Africa, 2015). PMTCT has dramatically decreased the number of infants testing positive for HIV and has become an important preventative intervention (Goga *et al.*, 2012; Ibeto, Giddy & Cox, 2014; Boivin *et al.*, 2015). A report from a study carried out during the period of 2009-2011, found the number of positive infant HIV tests decreased by 75.2% in selected clinics and hospitals in the Eastern Cape, Mpumalanga, and Kwa-zulu Natal (Grimwood *et al.*, 2012). The national vertical transmission rate for HIV (of exposed infants by 8 weeks of age) stood at 3.5% and in the Western Cape this rate was 3.9% (Goga *et al.*, 2012). However, these positive numbers did not reflect the risk of transmission in infants after 8 weeks of age – the same report states a national 18.1% of exposed infants at risk of transmission due to breast-feeding. Ibeto, Giddy and Cox's (2014) research highlighted several key concerns leading to failed PMTCT – including poor antenatal and post natal care. Each step in the PMTCT process needs to be followed intensively in order for there to be a possibility of eliminating mother to child transmission (Ibeto, Giddy & Cox, 2014). Recent research has also highlighted the loss of detectability of HIV in infants leading to false-negative test results (Mazanderani *et al.*,

2014). Hence, although medical advances are decreasing transmission rates of HIV in infants, this population is still at substantial risk and the population is still large enough to warrant research and interventions.

Furthermore, recent research has additionally picked up some ART drug side effects, which may be the cause of certain neurological deficits and may be detrimental to the child's motor development if undetected. Hauptfleish, Moore and Rodda (2015) reported two paediatric cases of motor ataxia caused by efavirens toxicity[3]. These motor difficulties were reversed once medication changes were made (Hauptfleisch, Moore & Rodda, 2015). Overall, judging from current literature and practice, further research is being carried out in this area and is an important consideration when investigating an HIV-positive child's development.

Rationale for the Study

Considering the early developmental challenges which HIV positive children face, including those on ART, and the increased number of those children surviving and now living with a chronic condition – the provision of various rehabilitation services is a necessity (Rogers, 2005; Schurgers *et al.*, 2010; Nixon & Forman, 2011; Devendra *et al.*, 2013; Potterton, Hilburn & Strehlau, 2016). Occupational therapists have the knowledge and skills to address these developmental skills (Case-Smith, 2005; Stevens, Kirsh & Nixon, 2014). Occupational therapy services are considered to be an integral part in rehabilitation especially in early identification and treatment of developmental and functional problems (Smith, Danoff & Parks, 2002; Schurgers *et al.*, 2010), specifically in the sensori-motor, perceptual-motor, cognitive, self-care, caregiver-support, and play areas (Pizzi, 1989; Anderson *et al.*, 1990). Yet, no scientific, published evidence has been generated by occupational therapists about their effectiveness in addressing the developmental concerns of the paediatric HIV population (Stevens, Kirsh & Nixon, 2014).

As much as research is lacking in the indication of the extent of developmental delay on children established on ART, there is also a deficit of research describing affordable and effective interventions to treat developmental delays in this group of children. Stevens, Kirsh and Nixon (2014) performed a scoping review of rehabilitation interventions for HIV-positive children and found no reported occupational therapy interventions in the

[3] Efaverins is one of the first-line ARVs used to treat children (National Department of Health South Africa, 2015). High plasma levels of efavirens, lead to toxicity, presenting as various symptoms and side-effects, including ataxia (Hauptfleisch, Moore & Rodda, 2015).

literature. They also highlighted the dearth of reported interventions in countries that carry the greatest burden of HIV.

Indeed, the challenge is how to best provide this occupational therapy support for the vast number of HIV-positive children in South Africa, when the professional platform of qualified occupational therapists working in South Africa is limited (Human Resources for Health South Africa, 2011).

The Kidzpositive Family Fund (Kidzpositive) is a non-governmental organisation (NGO) based in Cape Town, which aims to support the daily needs of children and families infected and affected by HIV. Occupational therapists employed by the NGO attend to the rehabilitation needs of this population, as there are insufficient occupational therapists employed at government health centres servicing this population. Despite extra Kidzpositive occupational therapy posts created to specifically cater for these populations in various centres in the Cape Town Metropole, the number of children requiring therapy is overwhelming and support to children on an individual basis is insufficient to reach all children made vulnerable by HIV and poverty (Richter, Foster & Sherr, 2006).

Identification of this need led to the Kidzpositive therapists collaboratively considering and developing a group based intervention that was play-informed and caregiver-focused as one possible and sustainable service delivery option. The intervention has been named: Play-informed caregiver-implemented home-based intervention (PICIHBI). The intervention involves monthly sessions with the occupational therapist and a group of HIV-positive children and their caregivers at the clinic. The intervention aims to empower the caregivers in promoting their children's development, self-care, playfulness, and academic learning in their home environments.

This study (see Aims and Objectives below) aimed to explore the impact of the PICIHBI option and provide unique data to research in this area. This study is novel in that it is an intervention study, adopting an occupational focus and covering a wider age group sample than other studies for children with HIV on ART in South Africa. The study explored the impact of occupational therapy with an appropriate cohort and provides much needed evidence to support the best practices in occupational therapy in this vulnerable population group. The study described in this dissertation is one in a group of studies comparing the impact of two interventions, the PICIHBI and conventional occupational therapy intervention, on various participation outcomes for the children and caregivers. The other

studies (see appendix A), occurring simultaneously, determine the learning outcomes, play outcomes of the children and the self-efficacy of the caregivers[4].

This study aimed to answer the following research question:

Research Question

Does a PICIHBI, facilitated by occupational therapists through clinic-based groups with caregivers, yield the same child developmental outcomes in pre-formal school-going aged children (approximately between 6 months and 5 years old) with HIV on ART, as a conventional one-on-one occupational therapy intervention?

Aim

The aim of the study was to evaluate whether a PICIHBI (experimental intervention) facilitated by occupational therapists through clinic-based groups with caregivers, yielded the same impact on children's developmental outcomes, compared with a standard one-on-one occupational therapy intervention (control), or not.

Objectives

The primary objective was to determine whether there is a significant difference in the total developmental quotient – on the Griffiths Mental Developmental Scales (GMDS 0-2) (ARICD, 1996) or Griffiths Mental Developmental Scales – extended revised (GMDS-ER) (ARICD, 2006) of children attending the experimental group and the control group.

Secondary objectives were to:

- describe the baseline developmental status of the children prior to any intervention.
- determine whether there was a significant difference in the quotients of children in the experimental group and the control group across the six developmental sub scales, namely eye-hand coordination, locomotor, language, practical reasoning, performance and personal-social.
- determine whether there was a significant difference in the total functional quotient (measured on the WeeFIM (Uniform Data System for Medical Rehabilitation, 2014)) of the children attending the experimental and control groups

[4] Researchers involved in the other studies are referred to as 'co-researchers'.

- establish whether there were significant correlations between the GMDS personal-social subscale quotient and the WeeFIM functional quotient.

Hypothesis

PICIHBI yields equivalent developmental outcomes for HIV positive children (in their pre-school years) on ART.

Null Hypothesis

PICIHBI does not yield equivalent developmental outcomes for HIV positive children (in their pre-school years) on ART.

Purpose

The purpose of this study was to generate evidence, which will guide occupational therapists as to the most effective intervention to improve the developmental outcomes of this specific population. If the evidence provided, showed the equivalency (or non-inferiority), or even superiority, of PICIHBI, it will guide which type of intervention should be tested for efficacy and replicated if providing successful outcomes, in other paediatric HIV clinics in South Africa. Significant improvements in child development linked to this intervention would inform the Departments of Health, Education and Social Development, guiding future early childhood development (ECD) projects, and highlighting specifically the contribution of occupational therapy to addressing the developmental needs of this vulnerable child population and their families.

Significance

In South Africa, ECD is the "umbrella term that applies to the processes by which children from birth to at least 9 years grow and thrive, physically, mentally, emotionally, spiritually, morally and socially" (Department of Education, 2001: 9). A fifth of South Africa's population is aged between 0-9 years old (Statistics South Africa, 2012). Similarly the Children's Act defines ECD as "the process of emotional, cognitive, sensory, spiritual, moral, physical, social and communication development of children from birth to school-going age" (The Presidency of the Republic of South Africa, 2010: 56–57). The Department of Education defines ECD as "a comprehensive approach to policies and programmes for children… with the active participation of their parents and caregivers with the primary purpose being to protect the child's rights to develop his or her full cognitive, emotional, social and physical potential" (Department of Education, 2001: 9).

ECD in South Africa is a recognized challenge that the government is committed to addressing (Department of Education, 2001; The Presidency & UNICEF, 2009). The biggest problems surrounding ECD in South Africa are access to ECD services and the quality of ECD education being provided (Department of Education, 2001; The Presidency & UNICEF, 2009). The government has committed to prioritizing the ECD in vulnerable groups – one of which is HIV infected children (Department of Education, 2001; The Presidency of the Republic of South Africa, 2010). They have also committed to support inter-sectoral efforts to support these vulnerable groups (Department of Education, 2001).

This research is therefore significant as it provides an opportunity to test the efficacy of an ECD intervention for this vulnerable group and explore if it would be a viable option for the government to support. It also provides key information on the developmental status of this age band of HIV positive children on ART, and provides a valuable opportunity to target developmental challenges in this population. Additionally, it produces evidence-based practice data for all occupational therapists working in this context. It will provide a clear understanding of the areas of difficulty and intervention options for occupational therapists to focus their role and contribution of therapy in this population. Assuming a positive outcome the study will highlight the need for the Department of Health to extend their rehabilitation services to these children and form stronger links with the Department of Education and Social Development.

Further Literature Review Informing the Study

Child development and the environment from an occupational therapy perspective

An occupational therapist's view of child development has already been outlined above (see 'Introduction').

Further, one of the core understandings of occupational therapy is the key influence of environments on the occupational engagement of an individual (Law *et al.*, 2005). Individuals cannot be fully understood without consideration of their environment (Hagedorn, 1995). Likewise, child development cannot be separated from the environment: the process of development is determined by "a complex interaction of genetic inheritance, environmental conditions and opportunities" (Hagedorn, 1995: 45).

Walker, Wachs and Gardner (2007) explain that environmental factors (such as poverty and associated social, health and nutritional issues) have additional confounding effects on

development of a child. Irwin, Siddiqi and Hertzman (2007: 7) go as far as describing that a child's environments are what "matter the most for their development". Sharma (2011) similarly concurs that "environmental factors become even more important determinants of the child's future in the presence of any biological risk" (Sharma, 2011: 163). Children who do not have the opportunity to build on their foundational developmental skills through active play experiences at home and in educational settings are at risk of negative experiences such as stigmatisation and teasing, and low confidence which impact negatively on their academic, social and emotional development (Rosenblum, Weiss & Parush, 2003; Poulsen & Ziviani, 2004).

Participation, stimulation and development of skills is strongly linked to the social environment of a child (Law, 2002; Law *et al.*, 2005), especially during the infant stages when they are largely dependant on their caregivers. The environment provided by family is closely linked and important to children and their development of occupations (Law, 2002; Case-Smith, 2005; Law *et al.*, 2005). This influence on child development is highlighted as significant factors in early child development theorists such as Vygotsky and Bronfenbrenner (Case-Smith, 2005; Law *et al.*, 2005). Occupational therapists are thus encouraged to use this social factor to achieve therapy goals and improve effectiveness of therapy by expanding interventions to include the child's caregivers and family (Law *et al.*, 2005).

Specific to South Africa, child development is compromised by various environmental factors – an estimated 58% of children live in income poverty, and are deprived of basic amenities such as water (34%), basic sanitation (31%), and nutrition (malnutrition = 37%) (Berry *et al.*, 2013). Socioeconomic disadvantages such as these, place children at high risk of delays in motor and cognitive skill acquisition (Richter, Foster & Sherr, 2006; Grantham-McGregor & Cheung, 2007; Walker, Wachs & Gardner, 2007; Biersteker, 2012). Opportunities to promote child development in early educational settings are limited in that only 16% of 0-2 year olds and 64% of 3-5 year old children are engaged in a form of early learning group programmes in South Africa (including playgroups, nursery school, community-based programmes and Grade R, excluding day mothers and individual caregivers) (Hall *et al.*, 2016). An earlier report separated out those of Grade R age, stating 46% of 0-4 year olds as enrolled in a form of early learning (both formal and informal) and 55% of children aged 5 attending Grade R (UNICEF, Department of Basic Education South Africa & Department of Social Development South Africa, 2011).

ECD in HIV-infected children is likely even further compromised as the majority of those living with HIV in South Africa live in informal areas (both urban and rural) and these areas

are under-resourced and lack basic amenities (Shisana *et al.*, 2014). A recent Ugandan study suggests that "within the context of poverty, the home environment may be even more important to child neurodevelopment among children affected by HIV as compared to other settings" (Bass *et al.*, 2016: 5–6) and found that the child's early home environment is an influence on specifically cognitive development (Bass *et al.*, 2016).

The impact of HIV on the developmental trajectories of children

HIV is known to have varied impacts on child development. The developmental impairments described in the literature reviewed include motor (gross and fine), cognitive, language, behavioural, emotional and social development (Foster *et al.*, 2006; Abubakar *et al.*, 2008; Baillieu & Potterton, 2008; Burns, Hernandez-Reif & Jessee, 2008; Sherr, Mueller & Varrall, 2009; Hilburn, Potterton & Stewart, 2010; Smith, Adnams & Eley, 2010; Potterton, Hilburn & Strehlau, 2016).

A review by Le Doare, Bland and Newell (2012) looked at the impact of HIV, HIV exposure and ART on the neurodevelopmental outcomes of HIV infected and HIV exposed uninfected infants and children. All the studies they reviewed showed lower mean neurodevelopmental scores in HIV infected children than in HIV uninfected children. Sherr, Mueller and Varrall (2009) published a systematic review (reviewing published works from 1988 to the beginning of 2007) of cognitive development and child HIV infection, and found that 81% of the studies reviewed, showed HIV having negative effects on neurocognitive development. In an updated review, looking at new studies on the same topic Sherr, Croome, Parra Castaneda, Bradshaw and Herrero Romero (2014) still found the majority of studies (80.1%) associated HIV with a damaging effect on cognitive development.

A study by Lowick, Sawry and Meyers (2012) used the GMDS-ER to determine the developmental levels of HIV infected pre-school children on ART, in Soweto, South Africa. The results showed significantly lower overall general quotient scores, and individual subscale scores when compared to a group of HIV uninfected children (Lowick, Sawry & Meyers, 2012). A more recent South African study also looking at pre-school children's developmental levels (using the GMDS-ER) and who were all established on ART, found delay across all subscales, with the exception of the personal-social subscale (Potterton, Hilburn & Strehlau, 2016). This study's results indicated less severe delays in gross and fine motor skills (locomotor and eye-hand coordination subscales) but greater delays were noted in the more cognitively reliant subscales (language, performance and practical reasoning subscales) (Potterton, Hilburn & Strehlau, 2016).

In a study with South African and Malawian children aged 4-9 years old, it was found that being HIV-positive has an increased risk for developmental disability (24.4%) versus HIV-negative (7.4%) when tested with the Ten Questions test (Skeen *et al.*, 2014). This assessment is a screening questionnaire for child developmental problems in speech, hearing, vision, motor, and cognition domains. The more specific increased risks were highlighted as delay in achieving motor milestones (33.8% vs. 6.3%), hearing difficulties (18.8% vs. 8.9%), speech problems (20.3% vs. 10.3%) and mental difficulties (28.4% vs. 13.1%) (Skeen *et al.*, 2014). Whether or not the HIV-positive children were receiving ART is not mentioned in the article. One would assume the children were not on ART as if the cohort were on ART, this would have introduced a further potential factor to be considered in their analysis.

Motor development seems to be particularly affected in HIV infected children not on ART. Results of a study by Baillieu and Potterton (2008) indicated that 77.5% of a sample of 40 HIV positive (not on ART) South African children aged 18 to 30 months presented with significant motor delays. Gross motor functioning was most affected in 85% of the sample and fine motor affected in 12.5% of the sample; cognitive delay was noted in 70% of the sample (Baillieu & Potterton, 2008). This was confirmed in another study with a larger sample size (n=122, aged 4-30 months) by Potterton, Stewart, Cooper, Goldberg, Gajdosik and Baillieu (2009) of which only 18 children were receiving ART. Motor development was delayed in 87% of the sample and 78% delayed in cognitive development (Potterton *et al.*, 2009). In a study to determine the neurocognitive and motor deficits of HIV infected ART naive children compared to a control group of HIV uninfected (aged 6-12 years) in Uganda (Ruel *et al.*, 2012) motor development was measured by the Bruininks-Oseretsky Test for Motor Proficiency (Second Edition). The results showed that HIV infected children scored significantly lower total scores than HIV uninfected children ($p = 0.003$) (Ruel *et al.*, 2012). Specifically, lower scores were seen in the areas of manual dexterity and speed agility (Ruel *et al.*, 2012). The HIV infected children also showed trends toward poorer performance in fine motor precision, fine motor integration, balance, upper limb coordination, and strength (Ruel *et al.*, 2012). As a conclusion the study highlighted the need for interventions to prevent such impairment in this older child population (Ruel *et al.*, 2012).

The impact of HIV on motor skills persisted in some studies even when children were receiving ART (Smith, Danoff & Parks, 2002; Ferguson & Jelsma, 2009) with particular challenges noted again in gross motor skills for HIV positive children on ART, aged 35 months to 73 months, living in foster homes and care institutions in South Africa (Jelsma,

Davids & Ferguson, 2011). This article additionally highlights the impact of different environments on the development of children (Jelsma, Davids & Ferguson, 2011).

Smith, Adnams and Eley (2010) found, using the GMDS with a Cape Town HIV-positive sample of children aged between 0-6 years old, that before starting ART and after 6 months of ART developmental quotients were all below the normal range. Particular low performance was noted in the locomotor, hearing and speech and performance subscales (Smith, Adnams & Eley, 2010). The commencement of ART had neither improved nor deteriorated their development (Smith, Adnams & Eley, 2010). Whitehead, Potterton and Coovadia (2013) (using Bayley III scales) found some improvement was noted in cognitive development scores in HIV infected children 6 months after started ART but this was not the case for language and motor development scores and they still scored significantly lower than an equivalent HIV-exposed but uninfected sample.

Another African study looking at the neurodevelopmental benefits of ART on Ugandan children 0-6 years old, found significant neurodevelopmental impairment in these children (Brahmbhatt *et al.*, 2014). However, they also noted that a longer duration on ART resulted in reduced risk of impairment in receptive language, expressive language and fine motor areas (Brahmbhatt *et al.*, 2014). This study provides positive evidence for improved motor and cognitive skills when on ART for a long duration but concludes that other interventions to improve and prevent poor development outcomes of this population are still urgently needed (Brahmbhatt *et al.*, 2014).

Independence in the occupation of self-care is a vital part of any child's development as without it children would find it difficult to participate in other occupations such as play, education, social interaction and in other contexts such as the family and community (Shepherd, 2005). There was a lack of research noticed in how HIV affects this area of development. Anderson, Hinojosa, Bedell and Kaplan (1990) however do specifically mention one aspect of self-care activities: feeding – in which engagement in the activity was interrupted by frequent infections due to pneumonia in HIV positive children. The paucity of research in the self-care area is of particular concern given occupational therapy's focus on this key occupation, the abundance of time spent doing the occupation and its great support of other occupations.

Early childhood interventions promoting child development in HIV-positive children living in low income contexts

Many studies investigating HIV positive children on ART advocate for the early intervention of child development programmes tailored to this population's specific needs (Burns,

Hernandez-Reif & Jessee, 2008; Smith, Adnams & Eley, 2010). It is recommended that such programmes should include a focus on the specific development, play and learning needs of the child but should also focus on enhancing caregivers' awareness of the child's strengths and needs as well as promoting caregiver child interactions (Anderson *et al.*, 1990; Ramugondo, 2004; Richter, Foster & Sherr, 2006; Burns, Hernandez-Reif & Jessee, 2008; Bass *et al.*, 2016). A focus on caregivers of HIV positive children is important as family structures are complicated by psychosocial and contextual stressors such as the death of a parent, the presence of foster parents and caregiver concerns about their own health as well as the health of their children (Anderson *et al.*, 1990; Ramugondo, 2004; Richter *et al.*, 2009; Munoz *et al.*, 2016).

A key component of ECD in South Africa should be the active participation from caregivers to support and develop the needs of their child (Department of Education, 2001), thus all ECD interventions should have an integral caregiver component. Engle and Black (2007) describe in their review – "Strategies to avoid the loss of developmental potential in more than 200 million children in the developing world" (Engle & Black, 2007: 229) – that the most effective interventions should include a focus on active parenting and have skill building components. These suggestions are supported by a Ukrainian study by Dobrova-Krol, van IJzendoorn, Bakermans-Kranenburg and Juffer (2010) indicating that the child's rearing environment (inclusive of caregiver stimulation and support) can have a greater impact on the child than the HIV infection.

Researched interventions encompassing the caregiving approach to promote child development of HIV positive children are reporting positive results. A South African study found positive cognitive and motor developmental improvements following a home stimulation programme developed by physiotherapists for HIV positive children (aged less than 2 years, 6 months) (Potterton *et al.*, 2010). In Uganda – a year-long caregiver training programme used to enhance child/caregiver interactions (with children HIV-exposed, aged 2-4 years) reported a positive effect on the child's development with significant improvements in language (receptive: $p=0.004$, expressive: $p=0.001$) and cognitive development ($p=0.006$) (Boivin *et al.*, 2013).

A recent South African physiotherapy study looking to improve motor and cognitive development in HIV children used an individually designed home-based physical activity programme and massage therapy versus a control of just massage therapy over a 6 month period in 1-36 month old HIV positive children eligible for ART (but not necessarily taking) (Khondowe *et al.*, 2015). The study had many limitations and many important details were not stated, but no difference between the control and experimental groups was noted in

their Bayley III scale scores after 6 months of caregivers administering the programme at home (Khondowe *et al.*, 2015).

Currently, there is on-going research in Uganda focussed on improving HIV child development through enhancing the caregiver's attentiveness to their child, by using a year-long meditational intervention structured training programme (Bass *et al.*, 2016).

A Cochrane review looking at home-base child development interventions for pre-school children from socially disadvantaged families, specifically looked at cognitive and socioemotional development, with physical development as a secondary outcome (Miller, Maguire & Macdonald, 2011). The study found no statistical significance in improving children's cognitive outcomes through the various study interventions, and insufficient evidence to analyse socioemotional and physical development (Miller, Maguire & Macdonald, 2011). Thus there is no compelling evidence to prove an intervention will or will not work.

Rationale for an occupational therapy intervention for HIV positive children and their caregivers

The complex combination of problems faced by children with HIV and their caregivers pose great risks to their meaningful engagement in occupations. A core occupational therapy principle is that occupations are essential for health. If individuals are not able to perform meaningful occupations because of issues within themselves (developmental delay, disease, disability) or the environment they experience occupational dysfunction which impacts negatively on their health and well-being (Wilcock, 1999).

Occupational therapy is well positioned to reduce the long-term effects of HIV by building skills in both children and their caregivers (Schurgers *et al.*, 2010). Occupational therapists provide caregivers and children with opportunities to improve the quality of their children's lives and foster their development (Anderson *et al.*, 1990). Occupational therapists are play experts who draw extensively on play as a means, i.e. the tool by which they promote child development (Case-Smith, 2005; Knox, 2005; Law *et al.*, 2005). Despite the potential vast contribution occupational therapy can provide, there is limited evidence to demonstrate the positive impact that occupational therapy can have for this population.

Chapter 2: METHODOLOGY

Introduction

This chapter presents and discusses the study design, population and sample. The two interventions will be described and the data collection tools and process will be outlined.

In summary: This study employed a randomised control trial study design testing and comparing the efficacy of two interventions: a control of conventional occupational therapy and the experimental PICIHBI. The sample consisted of two groups of randomly assigned children receiving only one of the interventions at monthly appointments. The children were assessed using the GMDS and the WeeFIM as outcome measures for child development that were measured at baseline, a mid-point and post the interventions taking place. A pilot study was performed before the study took place to establish inter-rater reliability.

Research Design

This study took the form of a randomised control trial. It was pragmatic in nature, single-blinded, and involved a baseline, mid- and post-test.

The participants were randomly assigned, using a 1:1 ratio, to either the experimental – PICIHBI, or control group – conventional one-on-one occupational therapy and assessed at two intervals (roughly six months apart) using the GMDS and WeeFIM. Assessors were occupational therapists trained in the assessments. They were blinded to group assignment and were not involved in the provision of either intervention. All assessment results were only examined and analysed once the post assessment period had been completed.

Ethics approval was applied for and granted by the Human Research Ethics Committee (HREC), Faculty of Health Sciences, University of Cape Town (UCT): HREC ref 773/2014 (appendix B). The larger research study in which this research project was nested also gained ethical clearance – HREC ref 560/2103 (renewed) (appendix B).

The Interventions

Experimental: PICIHBI

This intervention was designed by the Kidzpositive occupational therapists (of which the author of this dissertation is one) with the help and guidance from UCT's occupational therapy department, drawing on the action research methodology of a co-operative inquiry (Heron, 1996). Therapists entered into regular meetings discussing the occupational therapy needs of their clients and aims/goals of an intervention based on literature and their experience in their clinics. A basic framework was drawn up and therapists shared responsibility for designing various sessions. These sessions were then discussed as a group, reviewed and modified where needed.

An undergraduate study's unpublished results (Ayliffe *et al.*, 2013) examining caregiver knowledge and perception about play, further informed the content of the PICIHBI providing the play-informed perspective. Their study took place at various Kidzpositive-supported clinics, with caregivers of HIV-positive children. Their results highlighted that caregivers deemed play important, that adult involvement in play was important, children need toys to play, and finally that the caregivers believed children learn through play. However, caregivers held a poor understanding on the features and stages of play. Although they valued play and its importance, caregivers didn't always know how to provide the best-suited play opportunities for their children.

Following the draw-up and discussion of a basic framework of PICIHBI, the content and structure were piloted at one of the Kidzpositive clinics, trying various options of delivery. Throughout, the therapists met to discuss the sessions and roll out of the intervention instituting changes along the way. The format described below was determined to align best with what the therapists wanted to be achieved as well as aligning with the feedback from the caregivers.

The aim of the PICIHBI intervention centred on empowering caregivers to promote their children's playfulness, academic learning, development and self-care. There was a strong focus on transferring knowledge to the caregivers about development of their child and childhood occupations and how to encourage success in these occupations. It also provided a space for caregivers to express their experiences with their children. Given the stigma around being HIV-positive, the group created a safe space for caregivers to meet other caregivers in similar situations, share stories and learn from each other. Although this factor of camaraderie was only observed in some of the groups and dependant on those willing to share, it is felt the sense of 'not being alone' was evident throughout.

The intervention was divided into three groups that focused on specific age ranges: Toddler group (6 months-2 years), Pre-school group (3-5 years) and Foundation Phase group (6-8 years) to ensure the content for each of the groups was appropriate to these age groups. The research described in this dissertation focused on comparing the impact of the PICIHBI and conventional one-on-one occupational therapy interventions on the younger two groups (6 months to 5 years). The Foundation Phase group is covered in another research project (see appendix A) as this age group focuses more toward academic skills as an output, rather than child development.

The sessions were attended by child and caregiver dyads. The main focus of intervention during the PICIHBI sessions was on the caregivers and supporting them to stimulate their children's development at home. A group session had a maximum of eight dyads taking part. The entire programme consisted of ten monthly sessions, making the intervention last just under one year's duration in total.

The structure of the group sessions was divided into two parts (each 45 minutes long): 1. Teaching the caregivers about the core concept/skills relating to development and how to build these skills with their children at home. 2. Practical application of how to stimulate the skill with the children present. The second half of the session allowed for the caregivers to view modelling from the therapist as well as the opportunity to try activities and ask questions immediately. An appointed child minder looked after the children during the first half of the session.

The group session contents were planned by highlighting developmental, play and learning skills needed in these age groups. The 6-8 group sessions of the intervention were additionally aligned with the Department of Education's Curriculum and assessment policy statements (CAPS) goals for foundation phase. For a table outlining the group session topics see appendix C. For an example of session note and outline see Appendix O.

As many of the study families Kidzpositive supports are classified as low socioeconomic, they cannot always afford toys. Hence to supplement the sessions, a box of resources (a 'GO box') was developed, and used by each dyad/child. Play things/toys are instrumental in helping children learn through play (Knox, 2005) and deemed essential by the caregivers (Ayliffe *et al.*, 2013). The content of the intervention suggests that toys can be homemade, as it is known that the families cannot afford much beyond their basic needs. It was emphasised that one does not have to buy toys to stimulate one's child. There are some useful basic items that are helpful to use when stimulating one's child. The 'GO Box' was filled with these basic items to empower and motivate the caregivers. The items included in each 'GO Box' were explained in the relevant sessions with the caregivers (depending on

what the item was and how it could be used) and were handed out over the course of the programme sessions such that at the end of a group sequence the box was complete. The box items were specifically appropriate to the three age groups (for content of 'GO' boxes see Appendix C).

The PICIHBI intervention was attended by the participant dyads once a month at GSH. These sessions were, where possible, aligned to their monthly pharmacy or doctor appointments. After the initial assessment they attended five sessions over the following five months, then the mid assessment was performed. Following this, another five sessions over the next five months and then the post assessment was undertaken (Figure 1).

Control: Conventional occupational therapy

The control group intervention consisted of conventional one-on-one occupational therapy.

Conventional occupational therapy is directed at the child during individual occupational therapy sessions. Therapy goals and content are determined by assessment of the child's performance components. Case-Smith, Richardson and Schultz-Krohn (2005: 10) explain that occupational therapy intervention with children should focus on "improving functional performance, adapting activities or providing assistive technology, modifying environments, and promoting children's participation and preventing disability through education." Occupational therapy intervention with children also has playful characteristics as play is the main occupation for children (Case-Smith, 2005; Knox, 2005). Therapists use tools/toys/games appropriate for the child within the individual sessions with the child. The caregiver is not focused on in this intervention, although caregivers who are actively engaged with their children are given the option to be involved in sessions.

The child was seen once a month for a 45-minute session with the therapist at GSH and aligned with their monthly pharmacy or doctor appointments. The therapist was a different therapist to the one carrying out PICIHBI and was not involved in developing the PICIHBI, thus no knowledge about the content of the groups was known. Conventional occupational therapy usually begins with an initial assessment, to decide the occupational therapy needs of the child. As the therapist was different to the research occupational therapist assessors and to avoid unnecessary duplication of assessment, the conventional therapist had access to their initial assessment results. This intervention followed the same plan as the PICIHBI intervention – baseline assessment, five sessions over five months, mid assessment, another five sessions over five months, post assessment. The 'GO Boxes' were available to these children after ten sessions and post assessment (i.e. at the end of the study).

Study Setting

The study took place at the Groote Schuur Hospital (GSH) Paediatric HIV clinic, which Kidzpositive has been supporting for fourteen years. Children with HIV attend the clinic regularly to receive doctor/professional nurse examinations, medication, blood tests, counselling and any other needed health services (dietician, psychologist etc.). Previously, there was no occupational therapy service for the children at the clinic. Only children with additional diagnoses that were deemed to require intensive occupational therapy were referred to the GSH or Red Cross War Memorial Children's Hospital (RCCH) occupational therapy services. For a child well established on ART, attendance at the GSH clinic is once monthly for medication, with every three-month appointment including an appointment with a doctor/professional nurse. The study took place from April 2014 to October 2015.

Population

For this study, the population were all HIV positive children, pre-formal school-going age (aged between 6 months and 5 years old), on ART attending the GSH paediatric HIV clinic. The number of children attending the clinic at the time of recruitment in this age group was 72.

Sample

Inclusion Criteria

- Children must be HIV positive as a result of vertical transmission (mother to child) and receiving ART
- Children must be over 6 months of age and up to 5 years old at the time of recruitment
- Children not attending a WCED registered school at the time of recruitment

Exclusion Criteria

- Children with no identifiable regular caregiver.

Caregivers

Although this research focuses on children, the intervention requires caregivers to take part in the research as well:

Inclusion criteria

- Caregiver should be able to spend at least seven hours a week with the child
- Caregiver should be able to attend at least five out of the ten sessions

Exclusion criterion

- Caregivers with no legal authority to give consent

Sample Size

A non-inferiority margin was set at 6 points (using the intervention study Powell & Baker-Henningham, 2004), and a standard deviation of 5 was used to calculate the sample size. If there is truly no difference between the control and experimental interventions, then 24 (12 per group) participants are required to be 90% sure that the lower limit of a one-sided 95% confidence interval (or equivalently a 90% two-sided confidence interval) will be above the non-inferiority limit of 6 points.

Sample size was calculated using the online Power (Sample Size) Calculator created by Sealed Envelope Ltd. (Sealed Envelope Ltd., 2012)

Data Collection Tools

Demographic Questionnaire

A questionnaire was developed by all four of the researchers involved in the larger project to gather demographic, social and medical information (appendix D). This questionnaire was translated and back translated into Afrikaans and isiXhosa, the mother-tongue languages of the participants. Most of the information was caregiver reported. Information pertaining to the child's birth history and medical history was obtained from their Road-to-Health card (Caregivers were asked to bring this with to the initial assessment) and their hospital/clinic folders (access permission was requested in the permission letters: Appendix E).

Griffiths Mental Development Scales

The GMDS 0-2 (from birth – 2years) (ARICD, 1996) and GMDS-ER (2 – 8 years) (ARICD, 2006) was used to measure child development outcomes at baseline before the interventions

started, after five sessions of the interventions and when the interventions' (ten) sessions were finished (12 months after the baseline assessment) (appendix F).

The GMDS 0-2 was developed by a British psychologist, Dr Ruth Griffiths, in 1954 and only covered the first two years of life (ARICD, 2006). The GMDS 0-2 was later extended in 1960s to include children up to 8 years of age (ARICD, 2006). The test is now under the property of the Association for Research in Infant and Child Development (ARICD) founded in 1957. It consists of two sets of scales: one for children aged between birth and 24 months – GMDS 0-2 – last revised in 1996 (ARICD, 1996) and one for those aged between 24 months (2 years) and 96 months (8 years) – GMDS-Extended Revised (GMDS-ER) – last revised in 2006 (ARICD, 2006). The test is currently being revised and re-standardised to design a scale that will be continuous from birth to 5 years 11 months by Prof Louise Stroud from Nelson Mandela Metropolitan University in Port Elizabeth, South Africa on behalf of ARICD (ARICD, 2013), this is set to be released in 2016. For the remainder of this dissertation, both the GMDS 0-2 and GMDS-ER will be collectively referred to as the GMDS, unless otherwise specified.

The GMDS defines the concept of mental development as "the processes and rates at which growth and maturation of a child's attributes and abilities take place" (ARICD, 2006: 1). Although the test is focused on and titled 'mental development', Dr Ruth Griffiths firmly believed in a taking broad view when looking at mental development and its influences and interactions with other developmental areas such as motor, and social (Griffiths, 1954). This is similar to how occupational therapists view child development (Law *et al.*, 2005).

The developmental profile of the child is established by the allocation of scores for each item the child passes. The items are developmentally ordered. Scoring is determined through observing the child perform various standardised activities with standardised apparatus. A few items are scored by verbal report from the caregiver. There are various subscales that development is classified into: locomotor (subscale A), personal-social (subscale B), language (subscale C), eye-hand co-ordination (subscale D), performance (subscale E) and practical reasoning (Subscale F, only in GMDS-ER). The GMDS 0-2 outputs results in the form of age equivalents, sub- and general quotients and percentiles (ARICD, 1996) and the GMDS-ER outputs are percentiles, z-scores, age equivalents and quotients (ARICD, 2006).

The GMDS has been used and researched in many countries including South Africa (ARICD, 2006). It was developed for the UK population and has not been standardised or normed for a South African population. Validity in South Africa has been achieved by Luiz, Foxcraft and Stewart (2001) who also highlighted the test's cross-cultural validity. Van Rooyen

(2005) found no significant differences between a South African (n=129) and British sample (n=161) when comparing the general quotients, suggesting similar performance from both countries. When looking at the individual performance in each subscale: the South African sample achieved significantly better in locomotor and personal-social subscales (A and B), the British sample achieved significantly better in language, eye-hand coordination and practical reasoning subscales (C, D and F). There was no significant difference in the performance of performance subscale (E) (Van Rooyen, 2005). These results were, however, varied between the different age years of the children (ages 4-7) (Van Rooyen, 2005). The South African sample attempted to be representative of the whole South African population although in the end true representation was not achieved. However, the results were considered relevant for the study population.

Only health professionals trained by ARICD approved tutors are allowed to administer the test. Although clinical use is restricted to any trained clinician, trained occupational therapists are advised to administer the test under the supervision of a certified psychologist or paediatrician. For this study, the researcher (RJM)[5] was trained in November 2012 by Dr Lorna Jacklin (Appendix G) and was supervised by Dr Barbara Laughton, a neurodevelopmental paediatrician at the Children's Infectious Diseases Clinical Research Unit (KID-CRU), Tygerberg Hospital, with regular phone calls/meetings and constant email communication. Other therapists that helped collect data completed their training in January 2014 with Dr Lorna Jacklin.

WeeFIM[6]

The WeeFIM is the paediatric version of the Functional Independence Measure (FIM) and was developed in 1987 (Uniform Data System for Medical Rehabilitation, 2014). It is a measure of functional ability for children, aged 6 months to 7 years old, and highlights their level of disability within functional independence. The scale can also be used to track

[5] All further reference to 'the researcher' in this thesis refers to RJM, the student/author.

[6] The use of the WeeFIM® instrument to collect data for this research study was authorized and conducted in accordance with the terms of a special purpose license granted to Licensee by Uniform Data System for Medical Rehabilitation (a division of UB Foundation Activities, Inc., "UDSMR"). Licensee has not been trained by UDSMR in the use of the WeeFIM® instrument, and the patient data collected during the course of this research study has not been submitted to or processed by UDSMR. No implication is intended that such data has been or will be subjected to UDSMR's standard data processing procedures or that it is otherwise comparable to data processed by UDSMR. The WeeFIM® data set, measurement scale and impairment codes referenced herein are the property of Uniform Data System for Medical Rehabilitation, a division of UB Foundation Activities, Inc. The service marks and trademarks associated with the WeeFIM instrument are all owned by Uniform Data System for Medical Rehabilitation, a division of UB Foundation Activities, Inc.

changes over the course of rehabilitation interventions as well as provide an analysis of the outcomes of these interventions.

Both the WeeFIM and the FIM were developed by the Uniform Data System for Medical Rehabilitation (UDSMR) in the United States of America. The adult FIM items were adapted to take into account the developmental aspect (normal degrees of dependence) of children (Uniform Data System for Medical Rehabilitation, 2014). The latest revision of the measure took place in 2004. Training to perform the WeeFIM is self-study. The researcher performed an online credentialing process to ensure rating reliability.

The WeeFIM comprises of 18 items that measure functional ability in three areas: self-care, mobility and cognition (appendix H). A score indicative of the level of dependence is given, ranging on a seven-level ordinal scale from complete independence to complete dependence. It can be scored by directly observing the child or by interviewing a caregiver that is familiar with the child's everyday activities. The WeeFIM outputs functional quotients for the total as well as the different domains of self-care, mobility and cognition.

The WeeFIM is sold as a system with software to be an easily used monitoring tool of children's functional independence in a facility. Any health professional can use the WeeFIM, so long as they have received online credentials. As one of the occupational areas of occupational therapy is self-care and functional independence in this area, it is assumed the majority of users are occupational therapists. Although this is difficult to measure, it was gathered from the research outputs, that occupational therapists are the primary users although physiotherapists and doctors are also using it and publishing research.

It cannot be ascertained how widely used the WeeFIM is in South Africa. However, as the assessment is system based, only therapists employed at facilities or larger practices may be more inclined to purchase and use the assessment.

The WeeFIM has been found to be valid and reliable for an American population (Uniform Data System for Medical Rehabilitation, 2014). It has been widely used in other countries such as Turkey, China, United Kingdom, and various European countries. The WeeFIM has been used in various acute and chronic conditions including developmental disabilities.

A research license was bought by the researcher and approved by UDSMR for the duration of the study.

Data Collection

The researcher is fluent in English and Afrikaans and undertook basic isiXhosa lessons. Translators (HIV counsellors working for Kidzpositive) were identified to help with forward and back translation of information letters, consent forms, and demographic questionnaire from English into isiXhosa. They received payment for their services. Afrikaans versions of all forms were translated and back translated by first language speakers involved in the research project. Afrikaans and isiXhosa translations of the appropriate GMDS instructions and phrases used were received from Dr Barbara Laughton, who has used them in her research (Laughton, Springer & Grove, 2010; Laughton *et al.*, 2012). Two translators (with experience in working in an early childhood development centre) were also on hand to help the therapist perform the GMDS in Xhosa for those who required it. The translators used the isiXhosa translations supplied and were trained in exactly how to translate during the assessment to keep within the assessments guidelines.

The researcher oversaw and primarily held responsibility for the data collection of all the children in the population (72 children).

The researcher and four other trained assessors (who were also occupational therapists) performed the GMDS for the baseline assessments. One of the assessors assumed responsibility for providing the PICIHBI. To avoid un-blinding she did not assist with the mid and post assessments. The researcher and the three remaining assessors performed the GMDS for the mid and post assessments. As there were five assessors (including the researcher) involved in the administration the GMDS, inter-rater reliability was established first (see pilot study).

The assessors narratively recorded the functional independence of each participant according to the WeeFIM assessment categories. Only the researcher scored the WeeFIM assessment of each participant. Reliability of the researcher was established by completing the online credentialing system administered by the assessment's company – Uniform Data System for Medical Rehabilitation (see appendix I).

Pilot Study

A pilot study was performed to establish inter-rater reliability for the assessors of the GMDS. Twelve percent (16 children) of the larger study population number made up the pilot sample, 14 of these 16 children were the correct age for this study's population. These participants were recruited from an occupational therapy outpatient clinic (also supported by Kidzpositive) at Victoria Hospital (individual and institution permission gathered) and various other sources (individual permission gathered). The children were those already

needing the assessment and being seen for individual occupational therapy by the Kidzpositive occupational therapist at Victoria Hospital or another medical professional. The assessors took turns performing the GMDS, all observed the child together, but scored independently and did not discuss the scores. The assessments took place at RCCH, where the use of one-way glass consultation rooms was available. During this assessment period, certain items and scoring were clarified for the assessors to establish a consistent method of scoring for all the future research assessments. The scores were checked by the researcher to determine if any scores had been left out or calculation mistakes made. Clarifications and common scoring errors were written in a document and available to all assessors as well as placed in each assessment kit.

The scores were correlated to determine reliability once all assessments had been completed. A minimum level of 90% agreement between all five assessors' scores was targeted. Internal consistency coefficients using the Cronbach alpha coefficients were performed on the standardisation sample, in the UK, and the coefficients all exceeded the value of 0.70, the acceptable minimum value of reliability (ARICD, 2006). An intraclass correlation (two-way mixed) was used for this study as there were more than two assessors (Landers, 2015). Absolute agreement was assessed for. The raw scores of the five assessors were correlated as these represent the assessors' observations. The other GMDS scores (quotient, age-equivalent, z-score, percentile) are determined from the raw scores; these were double checked by the researcher.

While full results are presented in the results chapter, it was clear that the assessors achieved a high agreement and reliability (99-100%).

Recruitment

Children who attended the GSH paediatric HIV clinic, and met the inclusion criteria were invited to join the study. Recruitment took place mainly at the clinic when they came for their regular appointments. The researcher and co-researchers approached caregivers personally. An information letter in either isiXhosa, English or Afrikaans was provided and explained to those interested. Written informed consent was required from the caregiver. If the caregiver was not the parent of legal guardian of the child, permission from the parent or legal guardian was obtained before continuing.

Recruitment occurred over a 2.5-month interval (mid April to end of June 2014). As some of the population only attended the clinic every three months, they were contacted via telephone and an explanation of the research was given (using a translator when necessary). They were asked if they were willing to consent. An appointment to come into

the GSH clinic to be assessed was then set up. This verbal consent was however confirmed and established in written form when they attended their baseline assessment appointment (after the research had been re-explained clearly again in person). Caregivers were also telephonically contacted if they missed their clinic appointment date to explain the research and set an alternative date.

The population's clinic attendance dates and telephone numbers were obtained through their clinic files (access permission requested in permission letters: Appendix E). Individual's were excluded from the sample if they were uncontactable – defined as: a minimum of three attempts at phoning the caregiver, over different times of day, as well as a Kidzpositive counsellor attempting to contact them.

As this study was part of a larger research project, with some overlap in populations, the researcher was responsible for recruitment of 25% of the larger population size (25% of 160 participants = 40).

A total of 42 dyads gave consent to be part of the study.

Reasons for not wanting to take part in the study included: could not meet time commitments (n=4), transport issues (n=3), and caregiver language issues (n=2).

Reasons for not recruiting members of the population: child or caregiver did not meet the criteria (caregiver not consistent or legal: n=4), telephone number was not recorded/incorrect/invalid/out-dated and did not attend clinic during the recruitment and baseline assessment period (n=17). Of these 17 uncontactable dyads, 7 were already considered "lost to follow-up" by the clinic as they had missed their appointments, been uncontactable and had not returned to the clinic for more than three months.

Baseline assessment

After recruitment (telephonic or in person), appointments for baseline assessments were made with the caregiver for the dyad to attend. Assessment sessions were made within the existing clinic schedule when possible, to prevent additional time burdens on the caregivers and children. If this was not possible, the caregiver was given options of alternative assessment appointments that they could choose from. A contribution towards transport costs and snacks were provided to the dyads.

When dyads were recruited, each dyad was assigned a code (letter and number combination) protecting the anonymity of the participants. This code was assigned to assessment slots on a timetable – if the dyad chose that slot to be assessed they were assigned the code designated to the slot.

At this initial appointment biographical and demographic information was obtained, the WeeFIM completed and the GMDS was performed on the child with the caregiver present (this took approximately two hours). At the same appointment, assessments with regards to the other studies involved also took place either before or after the WeeFIM and GMDS assessment.

If a dyad did not arrive at the scheduled assessment appointment and they had not phoned the researcher to reschedule, they were telephoned and another appointment was made.

There were five qualified and trained assessors and two translators used to assess the participants.

A total of 39 baseline assessments were collected. Three dyads that originally had consented, decided to withdraw due to time commitments (n=2) and an extended period hospital admission (n=1).

Randomisation

The list of codes, from the recruited and baseline assessed participants, were randomly assigned a number (randomisation code) using the Research Randomizer program (Urbaniak & Plous, 2013) by a co-researcher not involved in the assessment.

Another program, Random Sequence Generator (Randomness and Integrity Services Ltd., 2016), then randomly divided the numbers into two equal groups: group 1 = experimental (n=19), group 2 = control (n=20).

An independent individual not involved in the study handled the assignment into the two groups. The allocation sequence was not seen by the researcher or any of the assessors.

The intervention occupational therapists had access to the allocation and randomisation codes. Dyads in the experimental group were then grouped according to their age into the toddler and pre-school PICIHBI groups, with no more than 8 dyads in a group. All dyads were assigned intervention appointments dates and then phoned by the intervention therapists to let them know. These appointments were aligned with their pharmacy or doctors appointments.

Intervention period 1

Five monthly sessions of intervention then took place (July-November 2014). Two different occupational therapists performed the PICIHBI intervention and the conventional one-on-one therapy. Due to unforeseen circumstances the therapist providing the conventional therapy had to resign at the end of September (the research was not a factor in their

resignation). Another therapist was appointed to provide conventional therapy from October to November. The PICIHBI occupational therapist was one of the Kidzpositive occupational therapists who developed the intervention. This therapist was one of the assessors for the baseline but unblinded herself to perform the intervention, thus was not used as an assessor for mid- or post- assessments. The researcher and other assessors were blinded to which dyads were receiving which intervention.

Mid assessment

All participants received an appointment for a mid-test after five sessions/months of intervention. These were aligned with their monthly pharmacy or doctor appointments if possible. If this was not possible, the caregiver was given options of alternative assessment appointments that they could choose from. A contribution towards transport costs and snacks were provided if dyads could not attend on the clinic days.

This assessment period was three months (beginning of December 2014 to end of March 2015), due to many of the participants travelling during school holidays and end of year festivities. At the mid assessment time point the WeeFIM and GMDS were repeated. Additionally, demographic questions pertaining to school were re-asked and recorded as this assessment period was at the start of a new school year. At the same appointment, assessments with regards to the other studies involved also took place either before or after the WeeFIM and GMDS assessment.

Four of the same assessors and the same two translators were used for this assessment.

A total of 31 midline assessments were collected. Following the baseline assessment: 3 the 39 participants were transferred to other clinics (TFO), 3 were uncontactable and were “lost to follow-up” for their clinic appointments (LTFU), and another 2 withdrew due to time commitments.

Intervention period 2

Another five monthly session of intervention took place (March-July 2015). A new therapist was assigned to provide the conventional therapy. The same therapist who provided PICIHBI during the first period, continued to provide it during this period.

Post assessment

A final post-test assessment was performed after another five sessions/months of intervention. The same approach was followed as the mid assessment scheduling.

This assessment period was undertaken over another three-month period (end of July – mid October 2015). The WeeFIM and GMDS were repeated and a few demographic details updated. Again, assessments with regards to the other studies involved also took place either before or after the WeeFIM and GMDS assessment.

The same four assessors and same two translators were used for this assessment.

A total of 28 (of 31) post assessments were collected. One child had been transferred to another clinic (TFO). Two children did not complete the post assessment as they did not attend three scheduled appointments and were unable to be contacted after this (DNA).

Inter-rater reliability

High agreement was established between the five assessors before the study began.

Assessors were constantly querying marking throughout all three assessment periods in order to achieve consistency. During both mid and post assessments, four of the assessments had more than one assessor present to monitor consistency of assessing. The GMDS manual and document written during the pilot study that contained marking clarifications was referred to throughout the assessments if differences between assessors arose. This was done to informally monitor inter-rater reliability for the duration of the study.

Data safety and monitoring plan

Data for the sample was captured on hard-copy forms initially. For demographic data the hard copies were then scanned to electronic format and kept on a password secured database, accessible to only the researchers involved in the larger project. GMDS and WeeFIM scores were recorded onto a summary table on a separate sheet of paper by the researcher. These were also scanned into electronic copies. This was done after each assessment period. The original hard copies did not leave the sites and were kept in locked filing boxes at GSH (these were separate from other studies taking place within the larger study). Only the researcher had access to these boxes. Only the researchers involved in the greater study had access to shared data – i.e. demographic data. The clinic managers and head nurse managed access to the offices, where the boxes were kept. Hard copies will be destroyed at the end of the study. Electronic files were protected by passwords that only the researcher knew. These files will be kept for as long as further analysis is needed, and

provided further ethical approval is granted by the UCT's Faculty of Health Science Human Research Ethics Committee.

GMDS and WeeFIM scores were calculated by the researcher and recalculated a second time. To ensure accuracy, another researcher calculated a sampling (14%) of the assessment scores. Discrepancies in the scores were highlighted and discussed. Once consensus on all scores was reached, the data were transferred to electronic format in a Microsoft Excel spreadsheet. Demographics were coded and transferred onto the spreadsheet as well. A co-researcher checked the hard copy data against the data entered on the spreadsheet on all entries of all participants to eliminate errors. The same was done for the inter-rater assessments before the main study was started.

As this study is part of a larger one, the researcher held responsibility for this data collection of this specific sample, with other co-researchers holding other responsibilities and A/Prof Elelwani Ramugondo, as the Primary Investigator, was accountable for the main project. The responsibility of running of the GSH paediatric HIV clinic fell to Dr Paul Roux.

Data Analysis

Missing demographic data was reviewed at baseline and made aware of to collect at mid- or post-assessments.

Data from participants followed an intention-to-treat analysis; their assessment results were analysed according to their assigned group, regardless of how many intervention sessions they attended (Kielhofner, 2006).

Data was initially captured in Excel spreadsheets (Microsoft Corporation, 2010). Spreadsheets were exported into SPSS Statistics (IBM Corp., 2015).

Descriptive data and graphs for baseline data, objective one, ancillary analyses of changes over time and dosage were calculated in Excel and SPSS. Non-parametric tests (Mann Whitney U, Wilcoxon Signed Rank) were used to calculate results for objectives two, three, four and the ancillary analysis of changes over time in SPSS. Objective five was analysed using the Spearman correlation co-efficient in SPSS. Ancillary analysis, to see the effects of dosage, school exposure and viral loads, was performed using mixed model and random effects analysis and was carried out in SPSS. Inter-rater reliability was calculated using intraclass correlations in SPSS.

Data analysis was completed by the researcher with advice, supervision and help from Rauf Sayed, Prof. Landon Myer (UCT Public Health), and Reshma Kassanjee (UCT Statistics Consulting Unit).

Ethical Considerations

Ethics approval was granted by the UCT Human Research Ethics Committee for the larger project in September 2013 and renewed in September 2014 (HREC ref 560/2013) and for this research project in October 2014 (HREC Ref 773/2014).

This study adhered to the ethical principles as outlined in the Declaration of Helsinki (World Medical Association, 2013).

Neither the assessment nor the intervention was invasive nor did they have any potential adverse effects. The choice to be a part of the study remained with the caregiver. No pressure was placed on the caregivers to choose to take part in the study.

The study had some time commitments for both the child and caregiver to attend the clinic once a month, as well as engage in what they had learnt from the intervention (if experimental group) at home. However, the compliance at home could not be monitored for practical reasons. The PICIHBI required 1.5 hours at the clinic every month, a total of 7.5 hours over five intervention months. The conventional therapy required 45min per month at the clinic, a total of 3.75 hours over five intervention months. Because the children taking part in PICIHBI only joined the session for 45 min, every child received the same amount of intervention time. The assessment required a time commitment of two hours for the dyad (at pre-, mid- and post-intervention). Thus the total time involvement over the study duration did not pose any social or economic risk to the participants. Participants received an appropriate transport reimbursement per trip to the clinic.

Benefits were potentially positive for the participants and outweighed any potential unknown risks. At the start of the study, few children at the GSH clinic received individual occupational therapy intervention. This study expanded occupational therapy services to this population, with additional capacity building focus for the experimental group. The PICIHBI is group-based which will allow for a more cost-effective intervention maximising skills transfer. This has the potential to strengthen the current national and provincial ECD efforts.

The dyads in the control group received the resources – the 'GO Box' – given to the experimental group, after the study finished. It was predetermined that if the results of the

study proved the PICIHBI to have similar or superior outcomes for the participants, those in the control group would have the opportunity to participate in new groups commencing at the clinic after the study was finished.

Informed consent process

Informed consent was obtained following the Declaration of Helsinki guidelines (World Medical Association, 2013). Approval from the Western Cape Department of Health (reference 2013 RP 185) and both hospitals was obtained first, before approaching dyads to participate (appendix E).

The researcher who was not a service provider at either clinic, approached the caregivers and they were provided with an information letter (in English, Afrikaans or isiXhosa) about the research (appendix J). An isiXhosa-speaking HIV counsellor, who was been identified to help with isiXhosa translation, was available and assisted with any additional clarification participants needed at both sites. The counsellor had received training from the Western Cape AIDS Training Information and Counselling Centre (ATICC) and had demonstrated knowledge of relevant medical and health terminology and the ability to maintain confidentiality.

Written consent was then requested if they were willing to participate (appendix K) at both sites. Refusal to take part in the study by either the child or caregiver was respected, and further access to services at the clinic was not be influenced. No information about the research was withheld from the participants.

Chapter 3: RESULTS

Introduction

In this chapter the results of the study are presented. Initially, participant flow and the demographic data are outlined. The results and analyses of inter-rater reliability and according to the study's objectives are presented. Ancillary analyses provided additional insight about the score changes over time and dosage of the interventions. A mixed model analysis was also performed to further explore the results.

Participant flow

The participant and data collection flow from the beginning of the study can be seen in Figure 1.

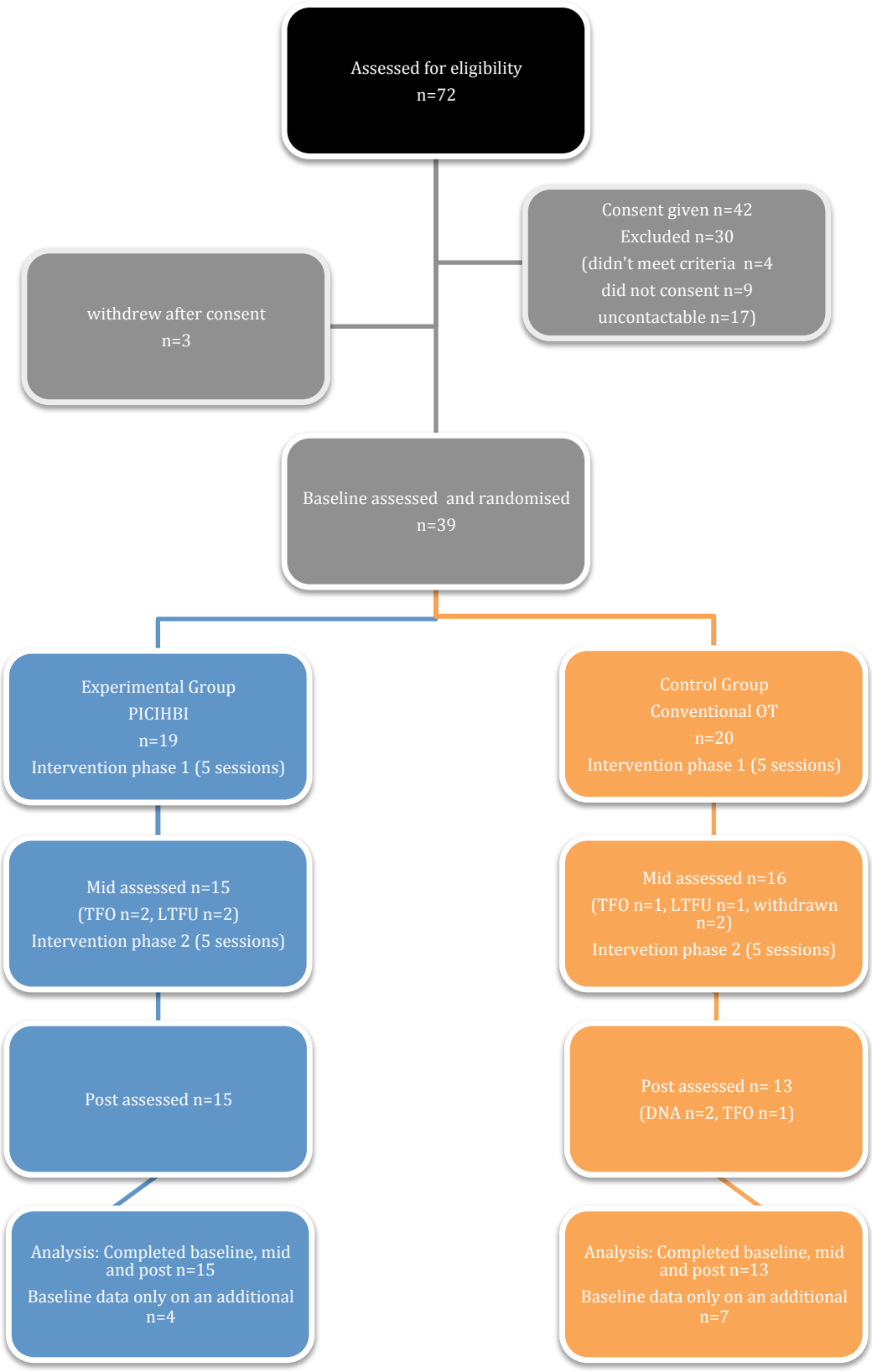

Figure 1: Study and participant flow diagram

Pilot study – Inter-rater results

The GMDS raw scores of five assessors across sixteen children were correlated. The intraclass correlations (two-way mixed) were performed within the subscales to establish if there were different agreements. Table 1 shows the results using an absolute agreement definition and the average measures:

Table 1: Inter-rater results

		Subscale						
	Age	A	B	C	D	E	F	Total GMDS
Intraclass correlation (average measure)	1	1	0.999	1	1	1	1	1
Range of difference (score points)	0	0-7	0-8	0-6	0-8	0-6	0-4	0-3
Average difference (score points)	0	1	1	2	1	2	2	1

Also included in the table are the ranges that the scores differed by and the mean difference. Raw scores only ever differed by a maximum of 8 points between any two assessors. On average, the raw scores between the assessors were a maximum of 2 points different. Age calculations were agreed upon 100% of the time across all assessors.

From these results we see the reliability measure varied between 0.999 and 1, meaning that 99-100% of the variance in the mean of the assessors is real. 99-100% of the variability in the raw scores captured represented the true score, and 0-1% represented a random variation. Therefore the five assessors had a high inter-rater agreement across the pilot sample.

Numbers analysed

The analysis included all randomised participants who completed all three assessments (baseline, mid- and post-test) – a total of twenty-eight participants (experimental n=15, control n=13). The study followed intention-to-treat analysis. There was no missing data found in the GMDS or WeeFIM scores over the three time periods. Some data was missing in some of the demographic data, however this data was not needed for analysis.

Demographic data

The total sample's age ranged from 6 months to 62.5 months at baseline. The majority of participants were isiXhosa 1st language speaking. A few participants had other

diagnoses/complications besides HIV. These ranged from physical impairments to common childhood conditions; 64.3% of the sample did not have any additional conditions/complications. Only four children had a confirmed HIVE diagnosis. Twenty (71.4%) of the participants had or were currently attending a form of rehabilitation therapy (physiotherapy, occupational therapy, speech therapy, audiology).

All participants were taking 1st line ART, meaning they had not proven resistant to any of their medications in their treatment regimes and had not had to change to different medications (2nd line). Nine (32.1%) of the sample had an unsuppressed viral load at baseline assessment, four of these children having only just started taking ART (<3 months)[7]. Five participants (55.6% of those unsuppressed), who were on ART for longer than 12 months, still had unsuppressed viral loads. At the post-test, the number of those with unsuppressed viral loads had decreased to four participants (14.3%), only one of these also had an unsuppressed viral load at baseline. Hence, eight participants had managed to suppress their viral loads and three had increased their viral loads, becoming unsuppressed.

At baseline, participants were either attending a crèche or at home with a caregiver (primary or another family member/friend). The younger participants (born 2012-2013) were at home with caregivers while older children (born 2009-2011) were also attending crèche facilities. When data was collected at the post-test, thirteen of the participants had started Grade R. Children should attend grade R the year they turn 6 years old. In this sample, this year was 2009. All, but one participant, born in 2009 were attending grade R facilities (reason unknown).

The sample characteristics and demographics are described in Table 2.

Table 2: Child sample demographic results

	Experimental			Control			Total		
Number	15			13			28		
Age (months)	Base	Mid	Post	Base	Mid	Post	Base	Mid	Post
Mean	39.3	47.4	54.8	50.4	58.7	65.8	44.5	52.6	59.9
Range	6-61	16-67.5	22-75.5	12-62.5	20-70	28-76	6-62.5	16-70	22-76
Gender									
Male	4 (26.7%)			8 (61.5%)			12 (42.9%)		
Female	11 (73.3%)			5 (38.5%)			16 (57.1%)		
Language									
English	3 (20%)			2 (15.4%)			5 (17.9%)		
Afrikaans	1 (6.7%)			0			1 (3.6%)		

[7] Once a child starts taking ART, it is expected that blood results will only reflect improvement after a couple months of treatment. Viral load tests are performed at month 6 of treatment to check ART effect, results from this help determine the future treatment plan (National Department of Health South Africa, 2015). If a child responds well to the ART, by 6 months, the viral load should be undetecable and suppressed (Woods & Eley, 2010).

Xhosa	11 (73.3%)		11 (73.3%)		22 (78.6%)	
Gestation						
Term	11 (73.3%)		8 (61.5%)		19 (67.6%)	
Premature (≤36weeks)	4 (26.7%)		4 (30.8%)		8 (28.6%)	
Unknown	0		1 (7.7%)		1 (3.6%)	
Other diagnoses/ complications						
HIVE	2 (13.3%)		2 (15.4%)		4 (14.3%)	
Cerebral Palsy (CP)	1 (6.7%)		1 (7.7%)		2 (7.1%)	
Epilepsy	0		1 (7.7%)		1 (3.6%)	
Failure to thrive	2 (13.3%)		0		2 (7.1%)	
Eczema	1 (6.7%)		1 (7.7%)		2 (7.1%)	
History of Otitis Media	1 (6.7%)		3 (23.1%)		4 (14.3%)	
Prenatal drug exposure	1 (6.7%)		0		1 (3.6%)	
TB History	3 (20%)		3 (23.1%)		6 (21.4%)	
None	9 (60%)		9 (69.2%)		18 (64.3%)	
During the day	2014	2015	2014	2015	2014	2015
With caregiver	6 (40%)	7 (46.7%)	3 (23.1%)	1 (7.7%)	9 (32.1%)	8 (28.6%)
With another caregiver/day mother	2 (13.3%)	2 (13.3%)	0	0	2 (7.1%)	2 (7.1%)
At Crèche	7 (46.7%)	2 (13.3%)	10 (76.9%)	3 (23.1%)	17 (60.7%)	5 (17.9%)
In Grade R	0	4 (26.7%)	0	9 (69.2%)	0	13 (46.4%)
Other therapies/ Specialists						
Speech	0		2 (15.4%)		2 (7.1%)	
Physiotherapy	3 (20%)		4 (30.8%)		7 (25%)	
Occupational therapy	5 (33.3%)		4 (30.8%)		9 (32.1%)	
Audio	0		2 (15.4%)		2 (7.1%)	
Dietetics	6 (40%)		5 (38.5%)		11 (39.3%)	
Neurologist	2 (13.3%)		3 (23.1%)		5 (17.9%)	
Orthopaedics	0		2 (15.4%)		2 (7.1%)	
ENT	0		1 (7.7%)		1 (3.6%)	
Hearing						
Not tested	12 (80%)		9 (69.2%)		21 (75%)	
Tested: no deficit result	3 (20%)		4 (30.8%)		7 (25%)	
Tested: deficit noted	0		0		0	
Vision						
Not tested	11 (73.3%)		11 (84.6%)		22 (78.6%)	
Tested: no	4 (26.7%)		2 (15.4%)		6 (21.4%)	

deficit result						
Tested: deficit noted	0		0		0	
Age when ART was started						
Mean	15.3 months		16.2 months		15.7 months	
Median	14 months		8 months		28 months	
Range	2-32 months		2-56 months		2-56 months	
Viral load	Baseline	Post	Baseline	Post	Baseline	Post
Supressed	10 (66.7%)	13 (86.7%)	9 (69.2%)	11 (84.6%)	19 (67.9%)	24 (85.7%)
Unsuppressed	5 (33.3%)	2 (13.3%)	4 (30.8%)	2 (15.4%)	9 (32.1%)	4 (14.3%)
Defaulting periods recorded	1 period = 3 (20%)		1 period = 1 (7.7%) 4 periods = 1 (7.7%)		1 period = 2 (7.1%) 4 periods = 1 (3.6%)	

Although the study participants in this study were the children, it is important to note some of their caregivers' demographics (Table 3), as they were an important factor in the experimental intervention.

Table 3: Caregiver sample demographic results

	Experimental		Control		Total	
Number	15		13		28	
Caregiver relationship						
Mother	11 (73.3%)		10 (76.9%)		21 (75%)	
Grandmother	2 (13.3%)		1 (7.7%)		3 (10.7%)	
Aunt	2 (13.3%)		2 (15.4%)		4 (14.3%)	
Caregiver age at baseline (years)						
Mean	34.8		33.7		34	
Range	25-66		23-56		23-66	
Caregiver Education						
Grade 5	1 (6.7%)		0		1 (3.6%)	
Grade 6	1 (6.7%)		0		1 (3.6%)	
Grade 7	0		1 (7.7%)		1 (3.6%)	
Grade 9	2 (13.3%)		0		2 (7.1%)	
Grade 10	3 (20%)		3 (23.1%)		6 (21.4%)	
Grade 11	3 (20%)		2 (15.4%)		5 (17.9%)	
Grade 12	4 (26.7%)		7 (53.8%)		11 (39.3%)	
2 years post Grade 12	1 (6.7%)		0		1 (3.6%)	
Caregiver Employment	2014	2015	2014	2015	2014	2015
Full time	2 (13.3%)	3 (20%)	3 (23.1%)	2 (15.4%)	5 (17.9%)	5 (17.9%)
Part time	1 (6.7%)	0	0	1 (7.7%)	1 (3.6%)	1 (3.6%)
Self employed	0	1 (6.7%)	1 (7.7%)	1 (7.7%)	1 (3.6%)	2 (7.1%)
Beadwork	0	2 (13.3%)	1 (7.7%)	2 (15.4%)	1 (3.6%)	4 (14.3%)

Unemployed: looking for work	7 (46.7%)	4 (26.7%)	7 (53.8%)	5 (38.5%)	14 (50%)	9 (32.1%)
Unemployed: Stay at home parent	4 (26.7%)	4 (26.7%)	1 (7.7%)	0	5 (17.9%)	4 (14.3%)
Unemployed: Retired	1 (6.7%)	1 (6.7%)	0	1 (7.7%)	1 (3.6%)	2 (7.1%)
Unemployed: Student	0	0	0	1 (7.7%)	0	1 (3.6%)
Monthly income of family (incl. grants)						
<R3500 at baseline	14 (93.3%)		12 (92.3%)		26 (92.9%)	

The majority of caregivers were the child's biological mothers. The caregivers' age ranged from 23 to 66 years old. The caregivers had varying education levels from Grade 5 to 2 years (at a tertiary educational facility) post Grade 12. Eight of the caregivers (28.6%) were employed in some form of work at the start of the study, this increased to twelve caregivers (42.9%) when data was collected at post-test. Twenty-six (92.9%) of the families participating were receiving less than R3500 income per month (this included government social grants), and were considered to have low socioeconomic status (according to the study definition).

Outcomes and analyses

Score explanations

Quotient: is a percentage of what the child achieved to score according to their age. A score of 100 means the child performed 100% of what they are supposed to at their age. In the United Kingdom (UK) the GMDS quotient scores are widely interpreted and classified into categories similar to that of IQ categories (personal correspondence, GMDS training course October/November 2012, Dr L. Jacklin) (table 4).

Table 4: UK GMDS quotient classification categories

Quotient score	Interpretation category
130+	Very superior
120-129	Superior
110-119	Above (high) average
90-109	Average
85-89	Below (low) average
70-84	Borderline mental retardation
50-69	Mild mental retardation
35-49	Moderate mental retardation
20-34	Severe mental retardation
0-20	Profound mental retardation

z-score: of 0 means the child's performance is average. A z-score of below -2 indicates a significant degree of developmental delay or learning disability on that subscale (ARICD, 2006). This is only a score outcome for the GMDS-ER (only children over 2 years old).

Raw score: is the score based on the number of items the child scored correctly in the assessment.

Significance: is the probability that the result did not occur by chance. Conventionally represented by a p-value and set at a threshold of 0.05 (Kielhofner, 2006). A p-value equal to or less than 0.05 indicates statistical significance and a low probability (≤ 5%) that the result was caused by chance. A p-value of more than 0.05 indicates a non-significant result and a higher probability (> 5%) that the result was caused by chance.

Summary of GMDS and WeeFIM scores at baseline, mid- and post-test

A summary of the control and experimental groups' mean performance and standard deviations (SD), over the three timepoints, is represented in Table 5.

Table 5: Control group and experimental group data summary

		Control Group (n=13)						Experimental Group (n=15)					
		Baseline		Mid-test		Post-test		Baseline		Mid-test		Post-test	
		Mean (min-max)	SD	Mean (min-max)	SD	Mean (min-max)	SD	Mean (min-max)	SD	Mean (min-max)	SD	Mean (min-max)	SD
GMDS	Locomotor/ A Quotient	81.05 (22.5-127.2)	30.5	81.38 (22.4-109.8)	25.3	84.92 (19.7-126.1)	29.3	81.74 (50.0-107.0)	16.6	77.85 (45.3-119.2)	18.2	82.22 (45.0-127.7)	22.0
	Personal-social/ B Quotient	92.96 (70.5-124.1)	14.8	87.99 (58.1-114.9)	15.5	93.59 (64.6-131.5)	15.9	95.13 (75.0-132.0)	16.9	94.58 (51.3-125.8)	18.1	97.27 (45.5-136.2)	21.2
	Language/ C Quotient	72.00 (43.1-122.0)	21.8	70.29 (51.2-102.2)	16.4	74.29 (50.0-93.8)	13.6	77.95 (50.0-121.0)	18.6	71.38 (42.6-100.0)	16.5	72.33 (36.4-90.0)	15.6
	Eye-hand coordination/ D Quotient	72.76 (52.8-93.9)	12.5	76.25 (64.0-108.0)	13.5	76.63 (57.4-90.9)	10.7	79.91 (59.8-113.0)	16.4	75.45 (57.4-99.0)	12.8	74.87 (46.2-93.0)	11.3
	Performance/ E Quotient	63.39 (41.7-133.9)	17.4	74.92 (51.4-148.8)	26.7	84.69 (50.0-134.3)	24.5	71.75 (48.0-104.0)	16.1	67.31 (41.7-86.8)	14.8	73.39 (37.1-96.5)	15.4
	Practical reasoning/ F Quotient	75.58 (58.6-88.6)	10.8	73.87 (53.4-91.1)	13.0	76.55 (50.0-91.1)	11.7	73.49 (54.0-96.4)	13.0	73.24 (47.0-100.0)	14.0	72.46 (40.9-86.5)	13.0
	Total Quotient	77.49 (54.9-95.6)	12.4	76.35 (52.3-99.3)	13.2	79.32 (56.3-99.3)	13.1	79.75 (56.8-113.0)	15.1	77.07 (48.7-100.0)	14.0	77.83 (41.7-92.9)	12.7
WeeFIM	Self-care	91.91 (66.8-107.2)	13.3	98.49 (70.0-126.7)	14.1	102.06 (84.1-149.5)	16.4	98.09 (72.7-120.0)	14.0	97.57 (72.2-135.7)	18.6	100.04 (69.5-124.6)	15.4
	Mobility	92.89 (30.4-107.0)	20.3	96.98 (73.4-105.0	10.9	98.62 (73.5-102.9)	8.3	92.94 (55.8-109.1)	15.1	100.23 (75.9-123.0)	10.6	98.73 (74.7-107.8)	8.9
	Cognition	80.31 (44.2-108.7)	20.4	76.45 (43.9-101.6)	18.8	79.71 (44.8-106.1)	15.5	80.17 (50.8-120.0)	14.8	71.78 (52.2-103.6)	16.4	76.37 (50.2-98.3)	13.8
	WeeFIM Total	89.16 (62.4-107.0)	13.5	92.42 (70.4-107)	10.5	95.06 (78.7-109.4)	8.8	91.97 (77.8-116.7)	11.2	91.99 (70.9-125.0)	14.0	93.11 (72.3-105.9)	8.8

Objective 1:

To describe the baseline developmental status of the children prior to any intervention.

Table 6 below shows the average and median quotient scores of the whole sample (n=28) at baseline. Included for the GMDS scores are the quotient classification categories that are used in the UK. Also shown are the numbers of children that scored a z-score below -2 for those aged older than 2 years (those younger than 2 years, do not score a z-score).

The highest scoring subscale is the personal-social subscale (B) – participants scored an average of 94.13% and the lowest scoring subscale is the performance subscale (E) – participants scored an average of 67.87%. These participants would be classified as a 'mild mental retardation' according to the GMDS UK classification categories. In all the other subscales the participants scored in the borderline category. Fifteen out of 23 participants older than 2 years of age scored a z-score less than -2 (65.2%) and were classified as developmentally delayed.

WeeFIM scores were higher than the GMDS averages, but followed a similar pattern to corresponding GMDS subscales. The highest score was the self-care subscale (95.22%) and the lowest was the cognition subscale (80.23%).

Table 6: Baseline results of whole sample (n=28)

		Quotient Average	Quotient Median	Quotient Classification category (UK)	Number of participants with z-score ≤-2 (n=23)
GMDS	Subscale A	81.42	80.5	Borderline	8 (34.8%)
	Subscale B	94.13	91.4	Average	1 (4.3%)
	Subscale C	75.19	73	Borderline	12 (52.2%)
	Subscale D	76.59	74.8	Borderline	12 (52.2%)
	Subscale E	67.87	63.7	Mild mental retardation	18 (78.3%)
	Subscale F	74.58	74.4	Borderline	10 (43.5%)
	Total	78.70	78.4	Borderline	15 (65.2%)
WeeFIM	Self-care	95.22	96.5		
	Mobility	92.91	100.3		
	Cognition	80.23	81.6		
	Total	90.67	92.1		

Figures 2 to 14 show the scatter plots and box-and-whisker graphs for each subscale (GMDS and WeeFIM) of the whole sample's performance, at baseline. No trends were noted.

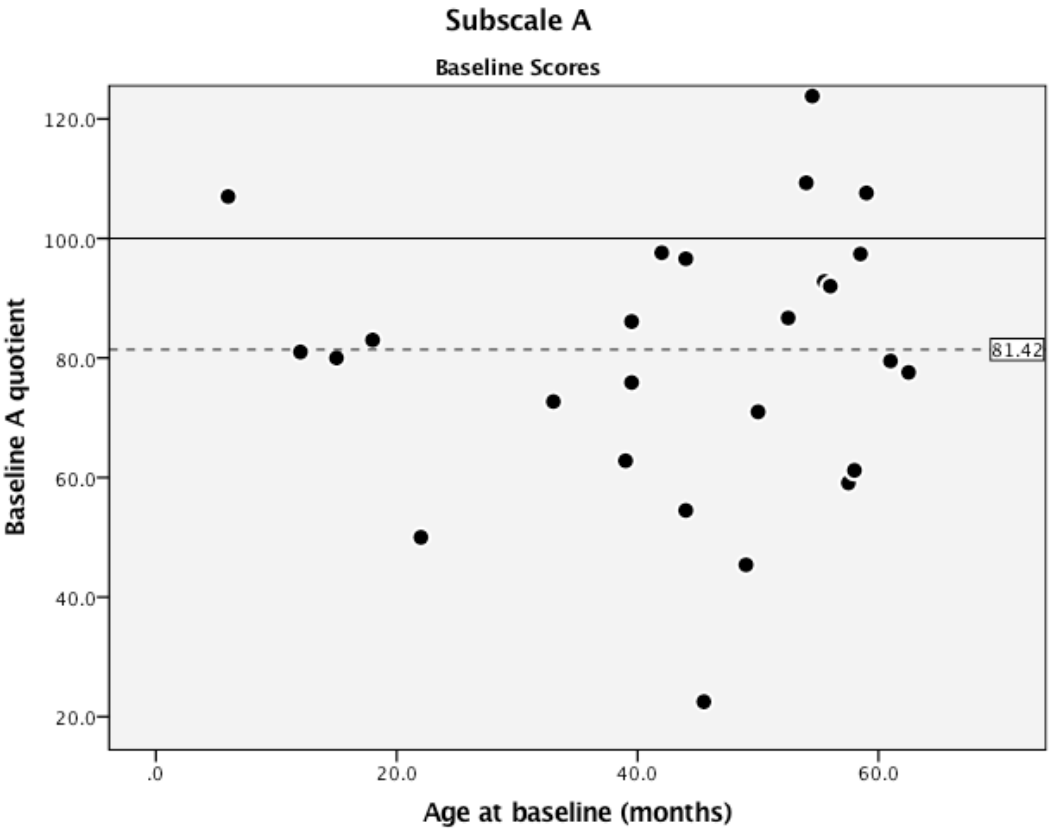

Figure 2: Baseline locomotor subscale (A) quotient over age

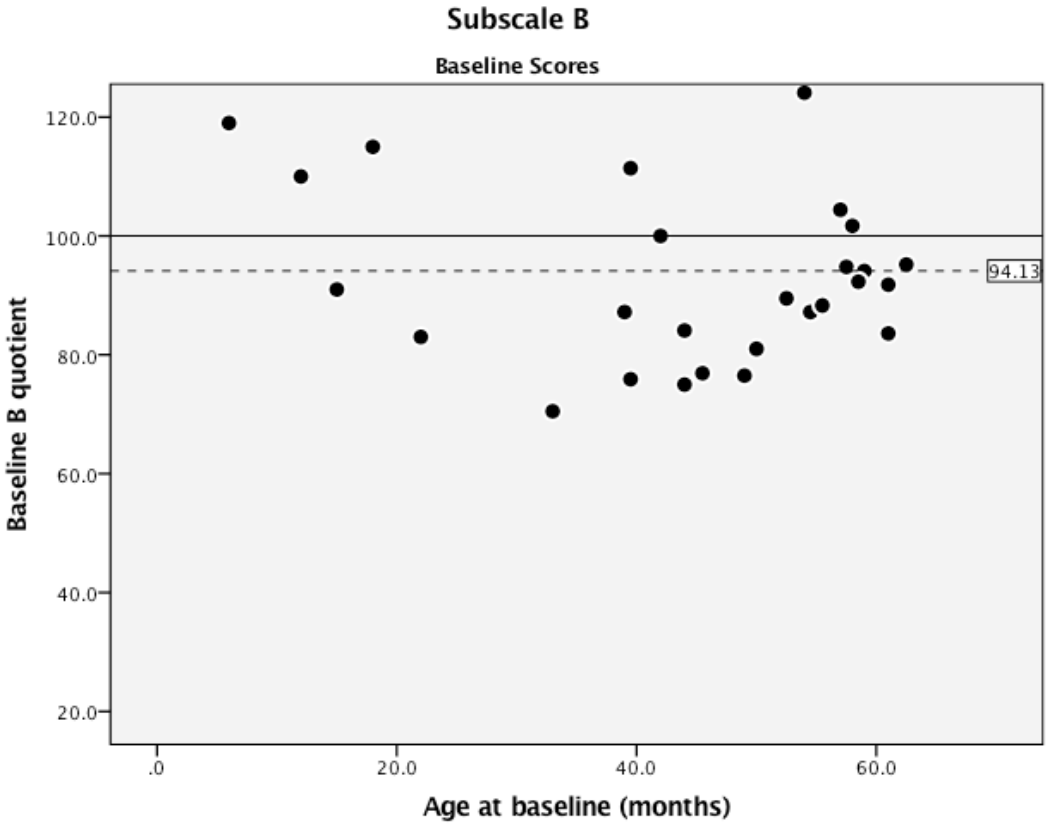

Figure 3: Baseline personal-social subscale (B) quotient over age

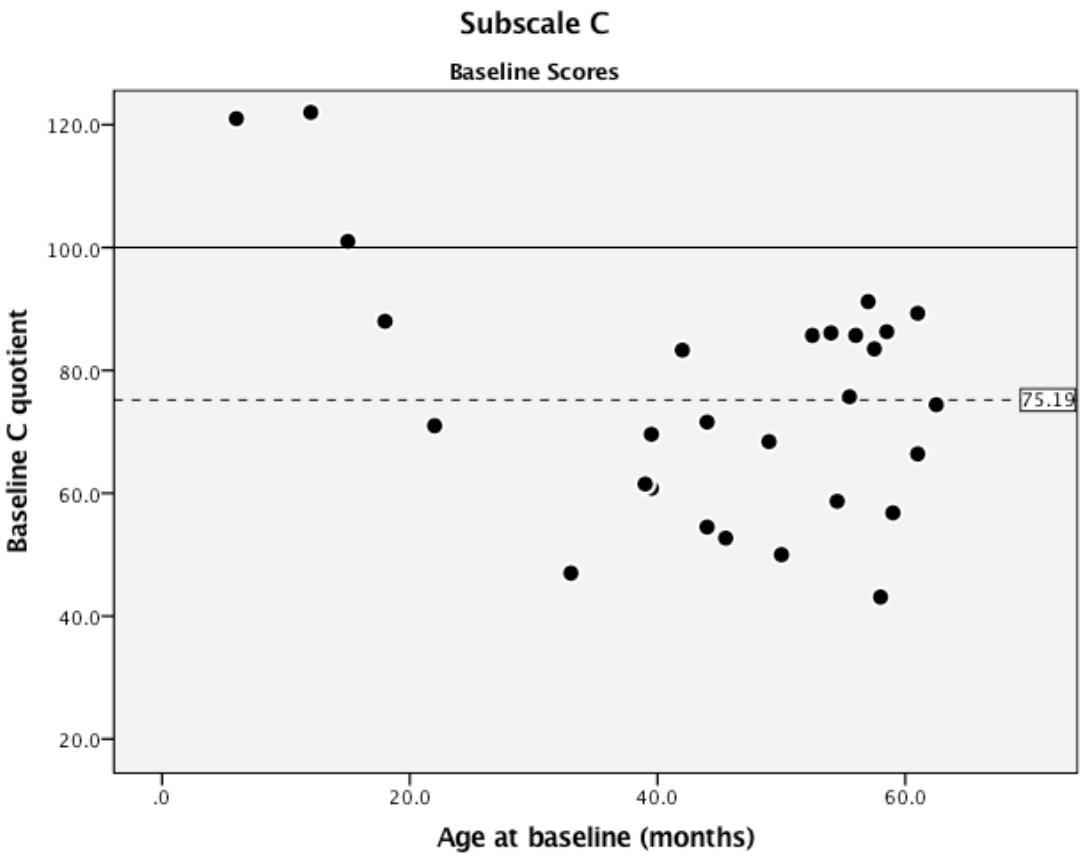

Figure 4: Baseline language subscale (C) quotient over age

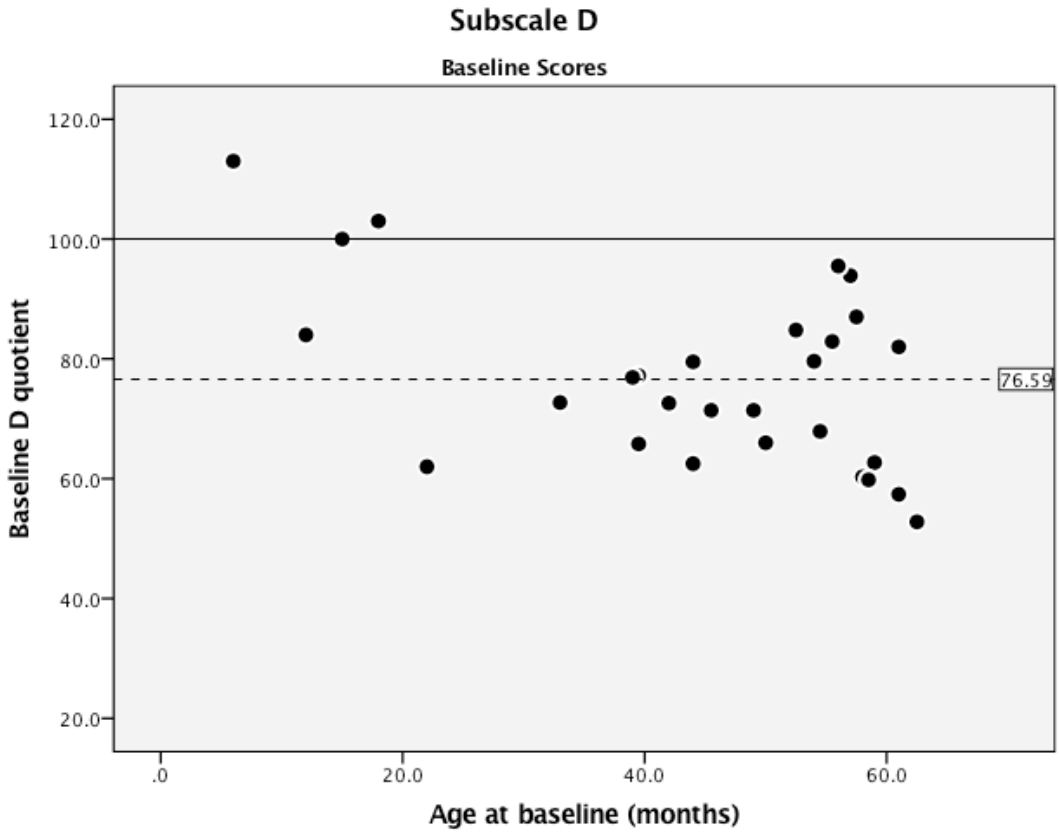

Figure 5: Baseline eye-hand coordination subscale (D) quotient over age

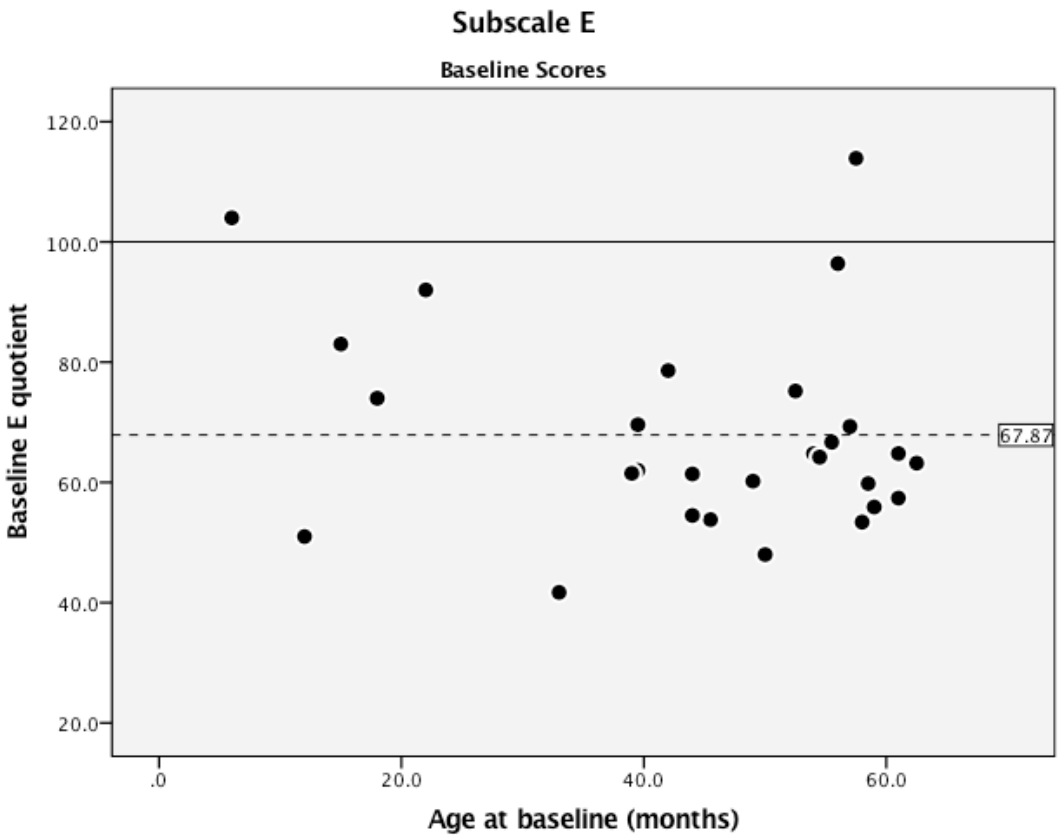

Figure 6: Baseline performance subscale (E) quotient over age

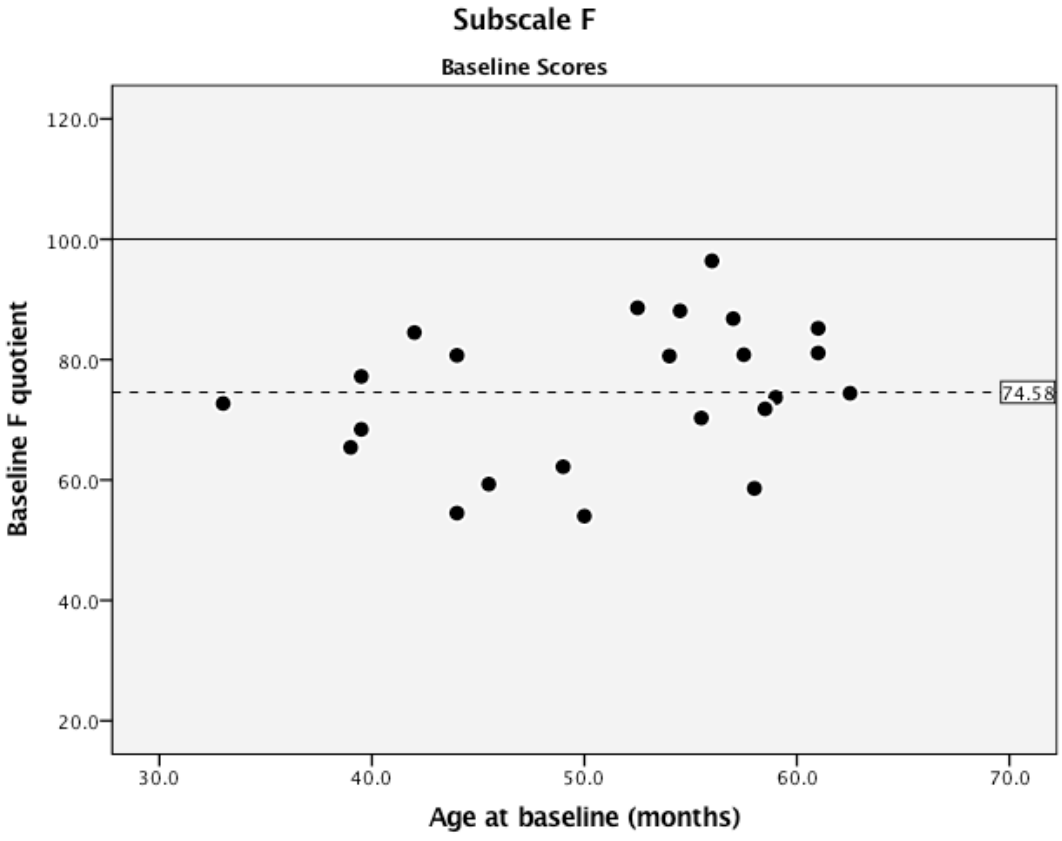

Figure 7: Baseline practical reasoning subscale (F) quotient over age

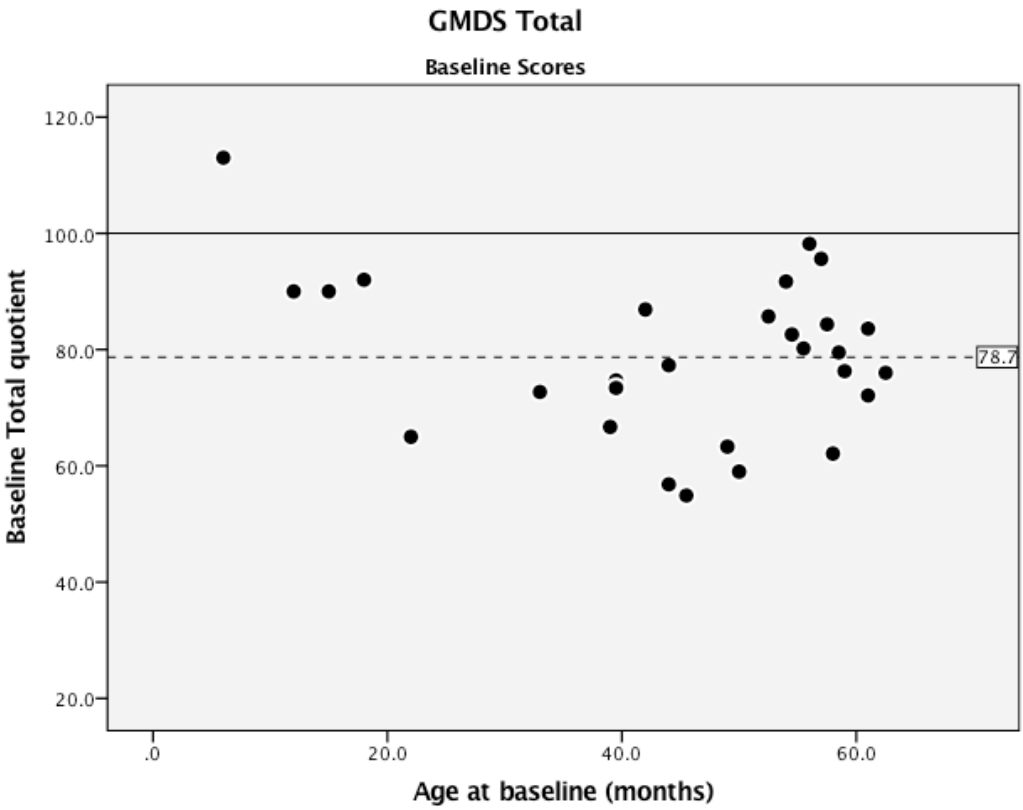

Figure 8: Baseline Total GMDS subscale quotient over age

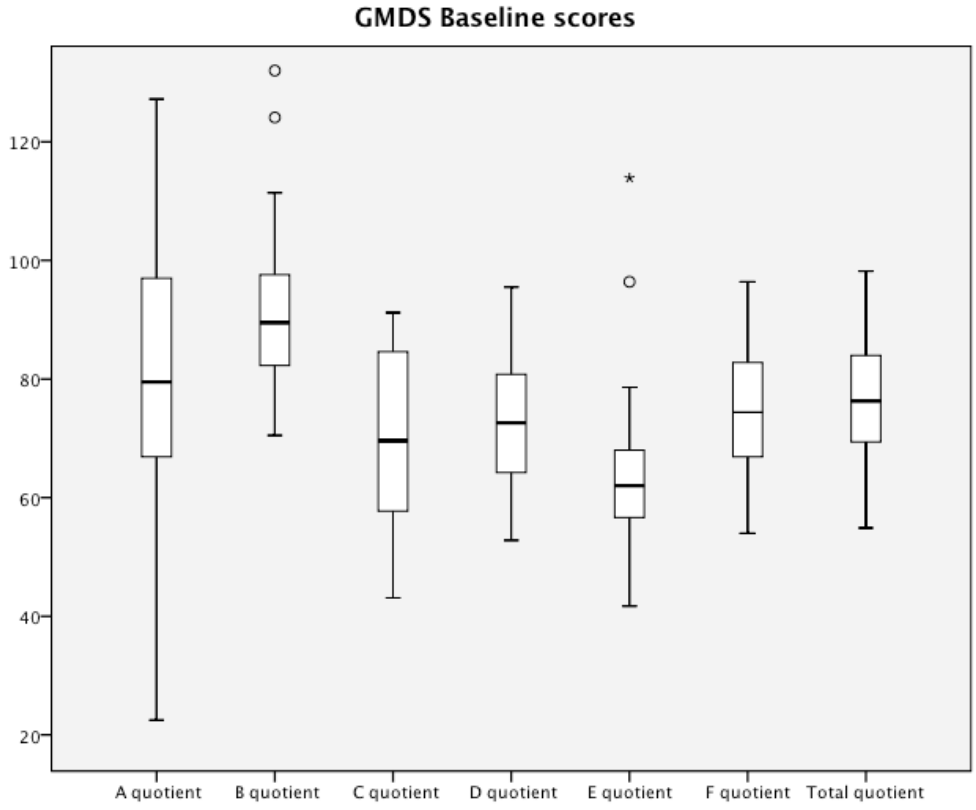

Figure 9: Box and Whisker plots of GMDS subscales and total quotients at baseline (showing minimums, maximums, means, standard deviations and outliers)

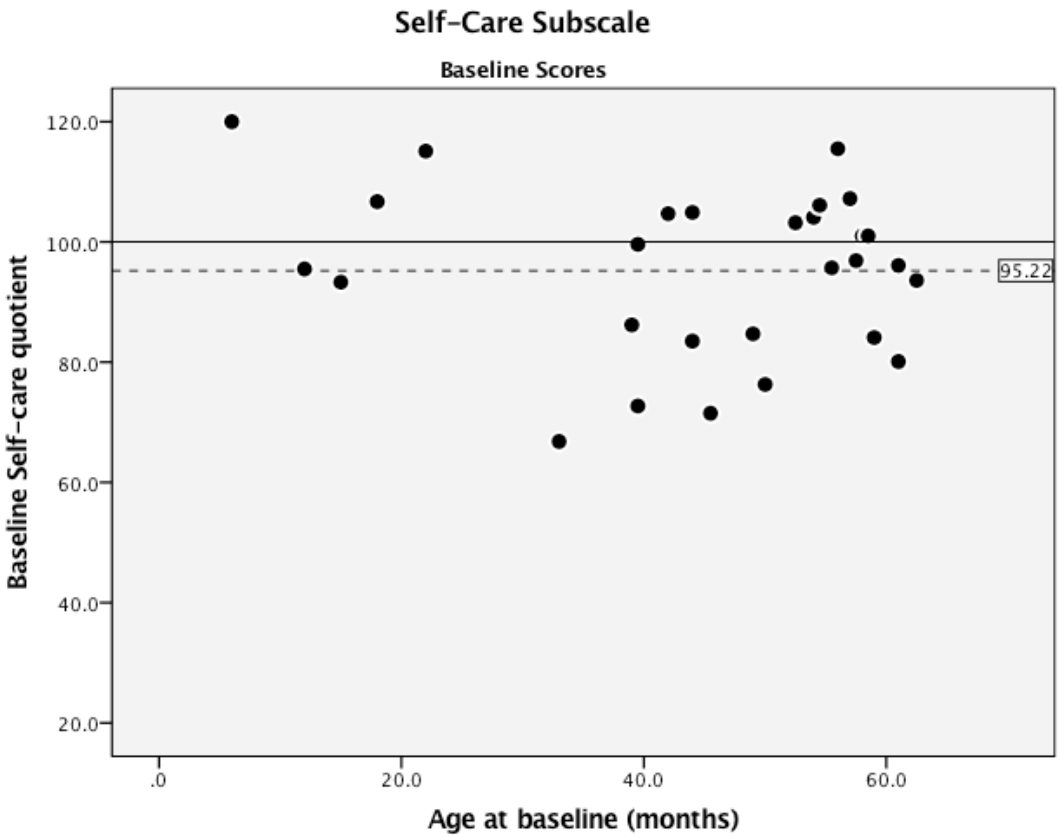

Figure 10: Baseline Self-care subscale quotient over age

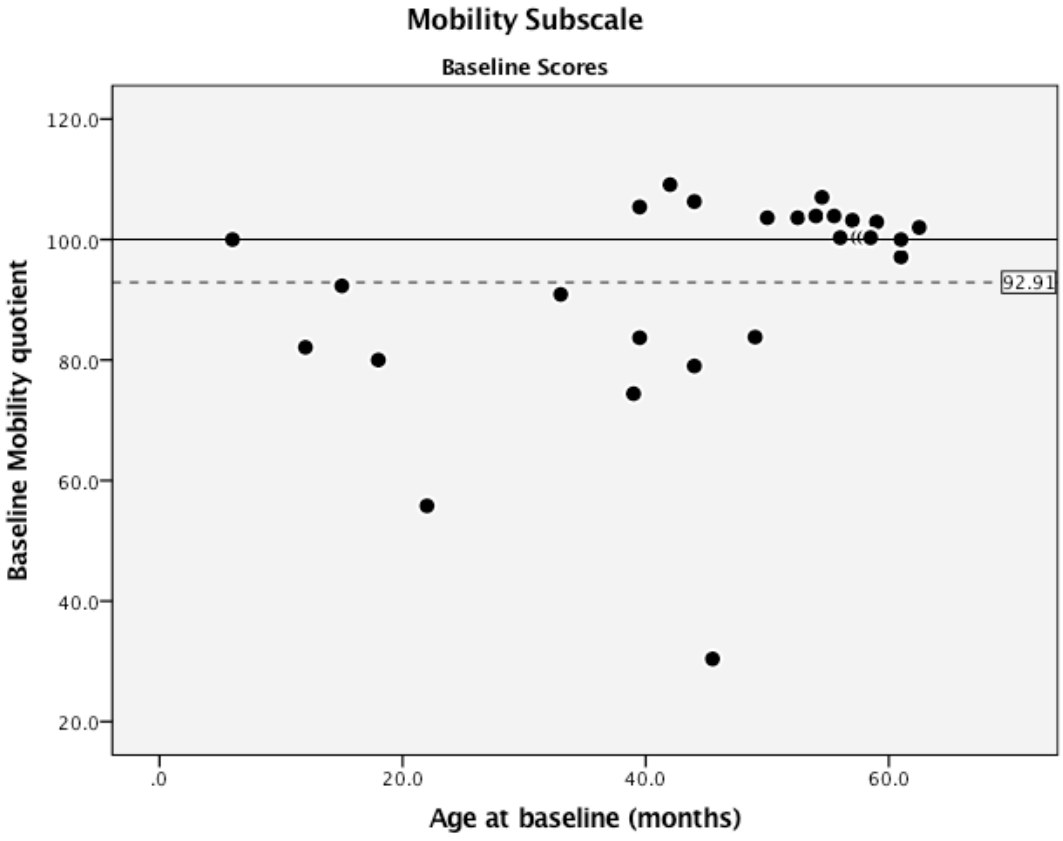

Figure 11: Baseline Mobility subscale quotient over age

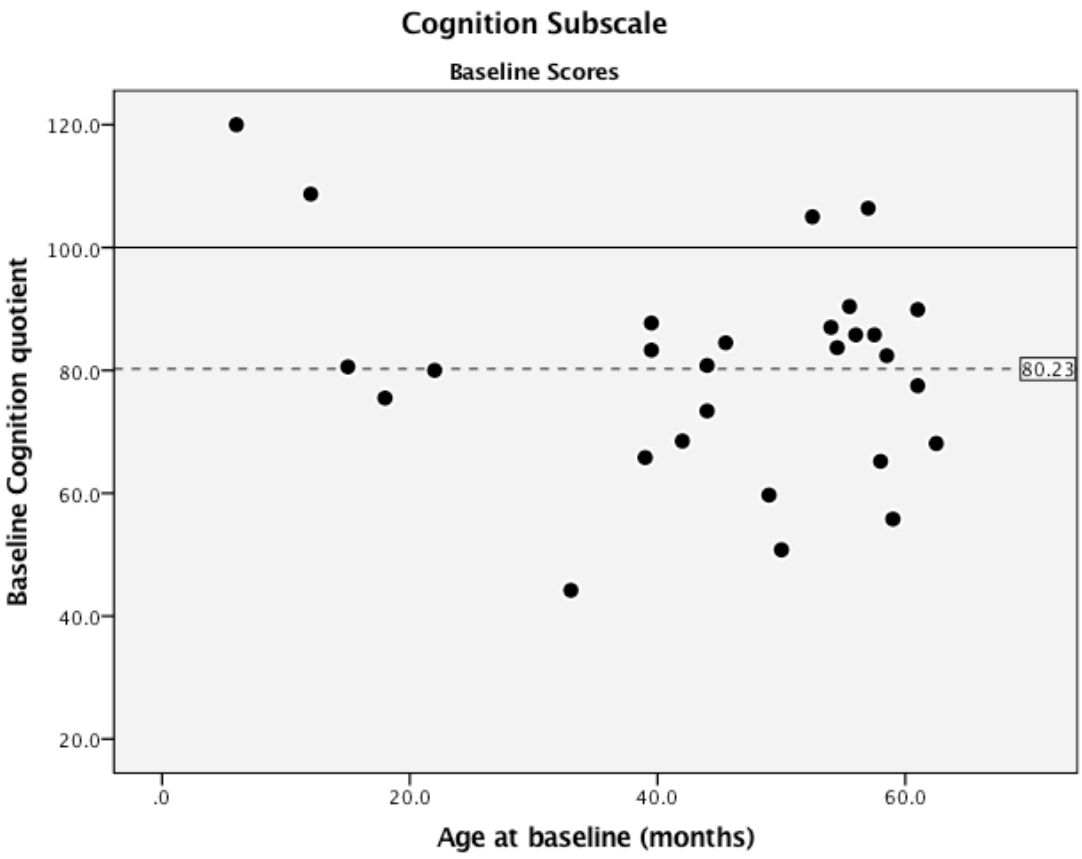

Figure 12: Baseline Cognition subscale quotient over age

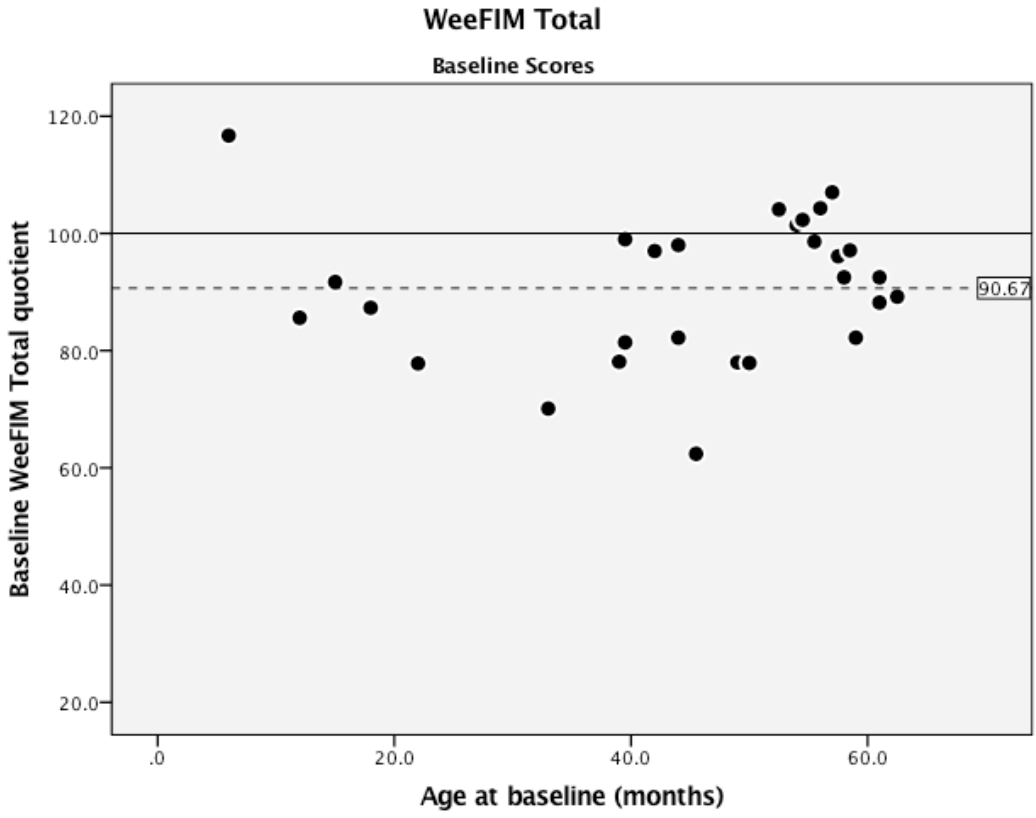

Figure 13: Baseline Total WeeFIM subscale quotient over age

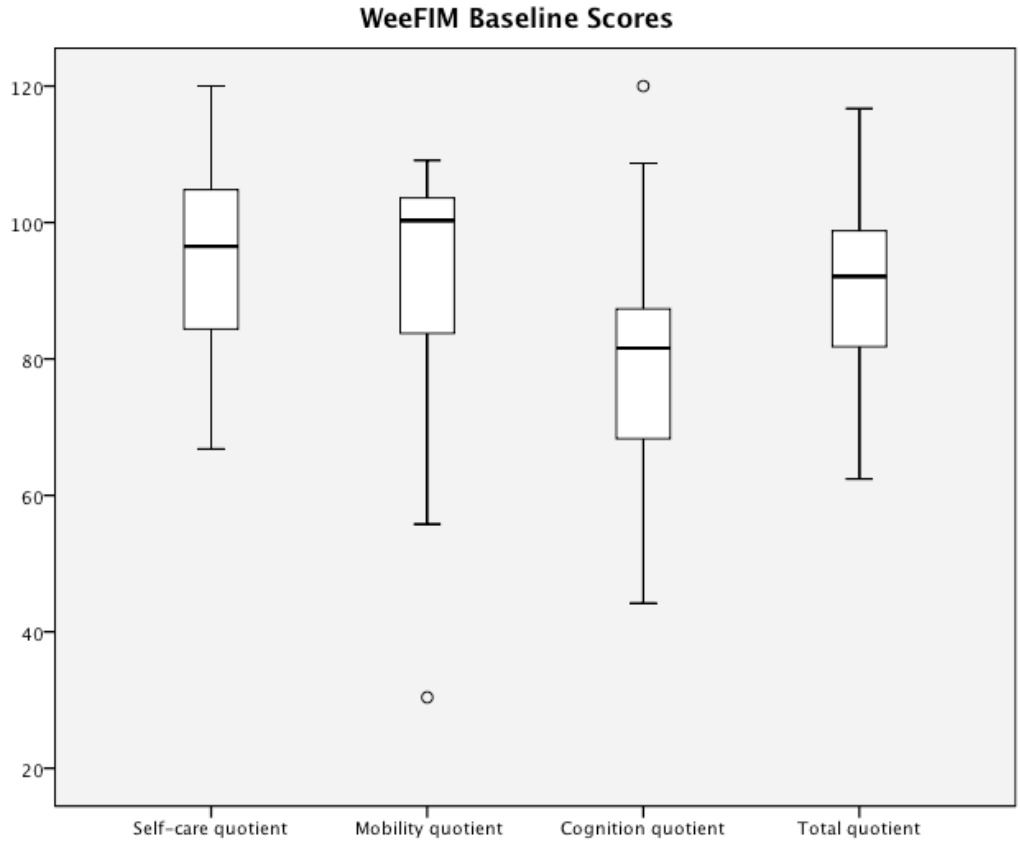

Figure 14: Box and Whisker plots of WeeFIM subscales and total quotients (showing minimums, maximums, means, standard deviations and outliers)

Determination of normality and choice of statistical tests

The Shapiro-Wilk test was performed on the quotient values at all three assessment points to determine if the data was normally distributed or skewed, which determined the choice of statistical tests for the remaining objectives. Significance of the results, conventionally represented by a p-value, is reported below in Table 7.

Scores below 0.05, highlighted in yellow in Table 7, are significantly skewed. The majority of the p-values were greater than 0.05 but standard deviation was high (ranged from 8-25 over scores) meaning the data wasn't skewed (i.e. was normally distributed but spread over a wide range).

Table 7: Normality significance results (Shapiro-Wilk)

		Baseline quotient		Mid test quotient		Post test quotient	
		p-value	SD	p-value	SD	p-value	SD
GMDS	Subscale A	0.971	24.7	0.507	22.6	0.390	25.4
	Subscale B	0.070	15.3	0.281	16.6	0.325	18.6
	Subscale C	0.156	15.0	0.102	16.6	0.069	14.4
	Subscale D	0.887	11.5	0.109	10.6	0.222	11.0
	Subscale E	0.002	15.3	0.001	22.0	0.048	20.9
	Subscale F	0.628	11.7	0.986	13.2	0.011	12.3
	Total	0.822	11.9	0.890	13.7	0.126	12.8
WeeFIM	Self-care	0.483	13.8	0.842	16.3	0.179	15.6
	Mobility	0.000	17.4	0.000	10.7	0.000	8.5
	Cognition	0.656	17.3	0.092	17.4	0.425	14.5
	Total	0.932	12.2	0.523	12.3	0.361	8.7

Although data indicated mostly a normal distribution a decision to use non-parametric tests was made because of the small sample size and high standard deviation. Non-parametric tests do not rely on data belonging to any particular distribution (Kielhofner, 2006).

- Mann-Whitney U test was performed to determine if there was a difference in scores in the two independent groups (experimental and control). A 95% confidence interval was used.
- Wilcoxon Signed Rank test was used to determine if there was a difference in repeat scores over the three time points for each intervention group separately. A 95% confidence interval was used.
- Correlations were determined using the Spearman co-efficient, which indicates the strength and direction (negative or positive) of a relationship between two variables.

Objective 2 (primary objective):

To determine whether there is a significant difference in the total developmental quotient of the GMDS of children attending the experimental group and the control group.

Table 8 shows the results of Mann Whitney U analysis and indicates no significant differences between the mean total quotient scores of each group ($p>0.05$) at each of the three time points.

Table 8: Objective 2 results – difference in total GMDS quotient

	Baseline		Mid Test		Post Test	
	Mann Whitney U	p-value	Mann Whitney U	p-value	Mann Whitney U	p-value
Total GMDS quotient	89.5	0.712	91.0	0.765	93.5	0.854

Objective 3:

To determine whether there was a significant difference in the quotients of children in the experimental group and the control group across the six GMDS developmental sub scales.

No significant difference ($p>0.05$) was found between the mean subscale quotient scores of each group (table 9).

Table 9: Objective 3 results – difference in GMDS subscale quotients

	Baseline		Mid Test		Post Test	
	Mann Whitney U	p-value	Mann Whitney U	p-value	Mann Whitney U	p-value
Subscale A	83.0	0.504	69.5	0.197	94.5	0.890
Subscale B	76.5	0.333	72.0	0.240	97.5	1.000
Subscale C	96.5	0.963	89.0	0.695	76.5	0.333
Subscale D	96.0	0.945	94.0	0.872	78.0	0.369
Subscale E	75.5	0.311	91.0	0.765	61.5	0.097
Subscale F	76.0	0.467	77.5	0.978	55.0	0.498

Objective 4:

To determine whether there was a significant difference in the total functional quotient (measured on the WeeFIM) of the children attending the experimental and control groups.

No significant difference ($p>0.05$) was found between the mean total functional quotient scores of each group (table 10).

Table 10: Objective 4 results – difference in WeeFIM total functional quotient

	Baseline		Mid Test		Post Test	
	Mann Whitney U	p-value	Mann Whitney U	p-value	Mann Whitney U	p-value
Total functional quotient	92.0	0.800	92.0	0.800	85.5	0.580

Objective 5:

To establish whether there were significant correlations between the GMDS personal-social subscale (B) quotient and the WeeFIM functional quotient.

The Spearman co-efficient was used to determine if there was a correlation between the GMDS subscale B and total WeeFIM functional quotient. The correlation co-efficient was 0.382 ($p<0.0001$). Hence, the two subscales are significantly positively correlated but with a moderate strength.

Figure 15 shows the scatter plot displaying the correlation.

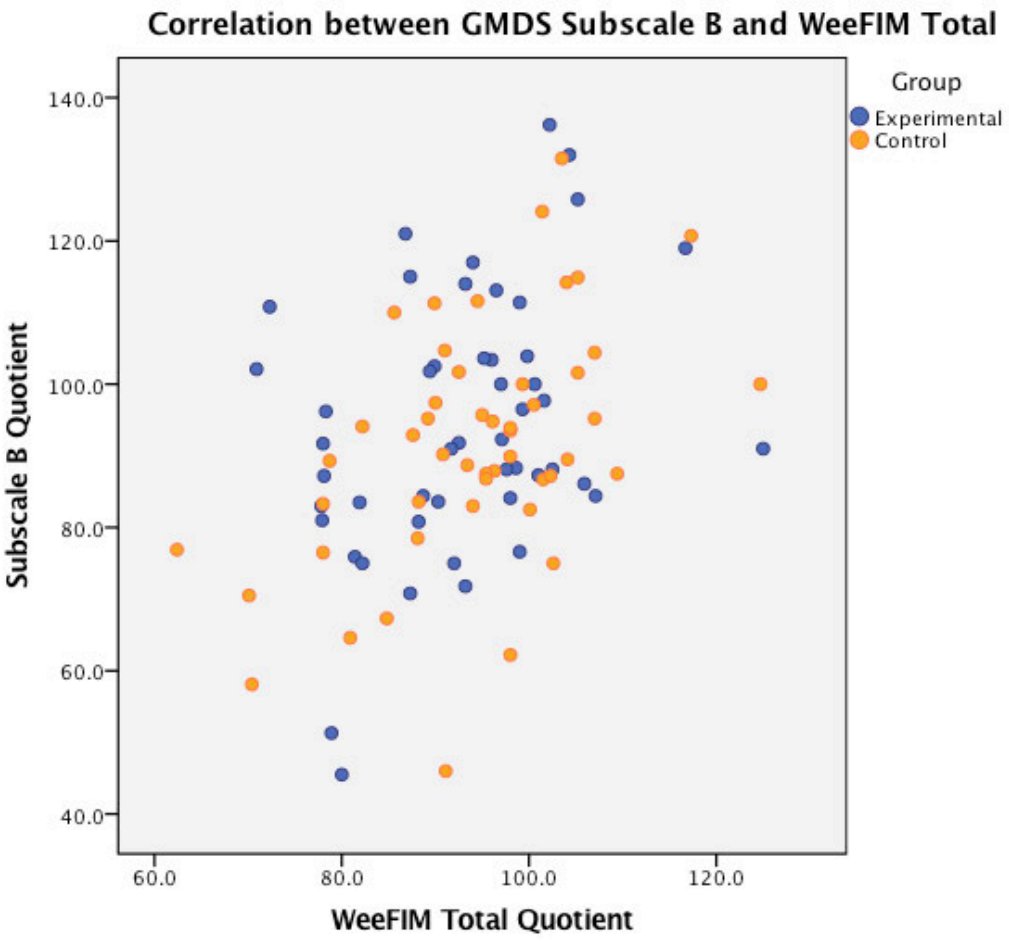

Figure 15: Scatter plot of correlation between the GMDS personal-social (B) and WeeFIM total quotients

Ancillary analyses

Score changes over time

Table 11 shows the post-test summary results of the whole sample after receiving interventions. When compared to Table 6, small increases and decreases can be seen in the different subscales. Performance (subscale E) had the largest increase (10.77 points) and resulted a change of classification category as well. The total percentage of children with <-2 z-scores decreased from 65.2% to 53.6%. This indicates the effect of either occupational therapy intervention.

Table 11: Post-test results of whole sample

		Quotient Average	Quotient Median	Quotient Classification category (UK)	Number of participants with z-score ≤-2 (n=27)
GMDS	Subscale A	83.48	85.8	Borderline	7 (25.9%)
	Subscale B	95.56	96.8	Average	2 (7.4%)
	Subscale C	73.24	77.4	Borderline	11 (40.7%)
	Subscale D	75.69	75.7	Borderline	19 (70.4%)
	Subscale E	78.64	79.1	Borderline	13 (48.1%)
	Subscale F	74.43	78.3	Borderline	13 (48.1%)
	Total	78.52	82.7	Borderline	15 (53.6%)
WeeFIM	Self-care	100.98	101.5		
	Mobility	98.68	101.8		
	Cognition	77.92	78.3		
	Total	94.01	94.9		

The below spaghetti plot graphs (Figures 16 to 26) track each individual participant's quotient change over time. Generally, no overriding trend was seen in the trajectories of the quotients across the time points.

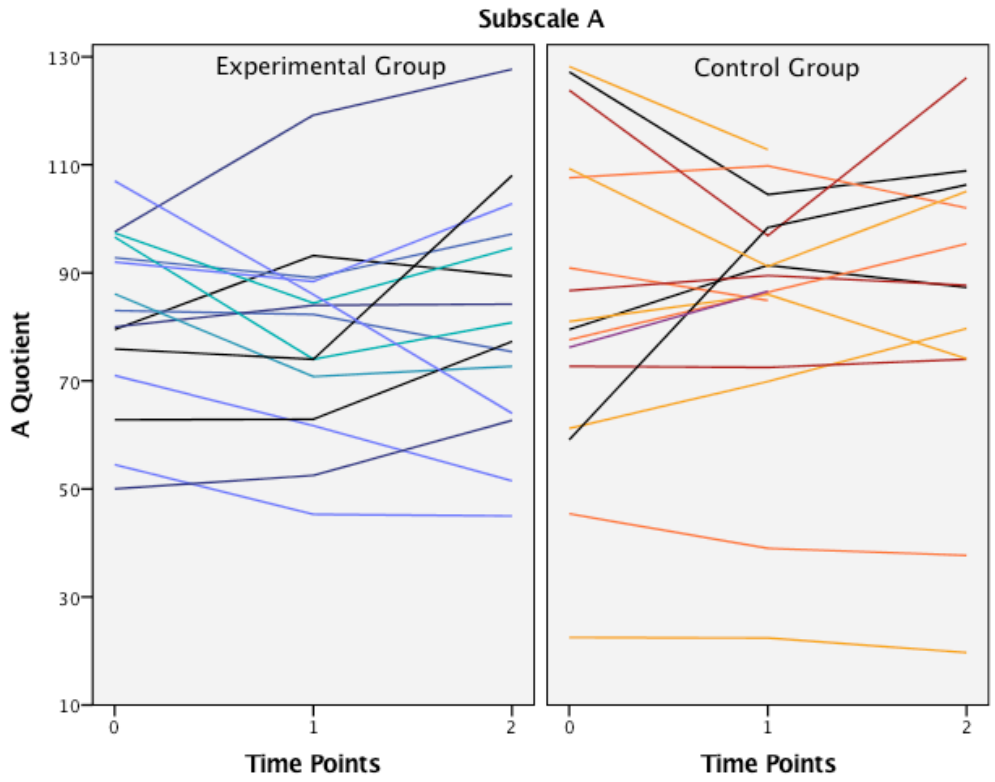

Figure 16: Spaghetti plot graph of locomotor subscale (A) quotient in both groups over three time points

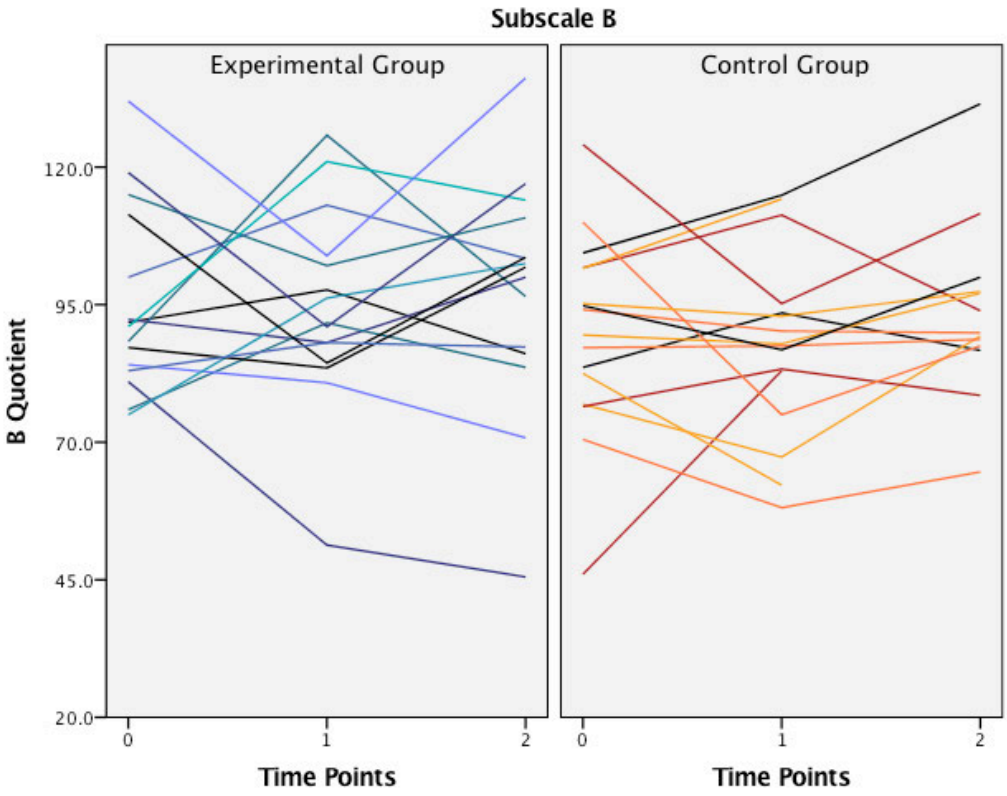

Figure 17: Spaghetti plot graph of personal-social subscale (B) quotient in both groups over three time points

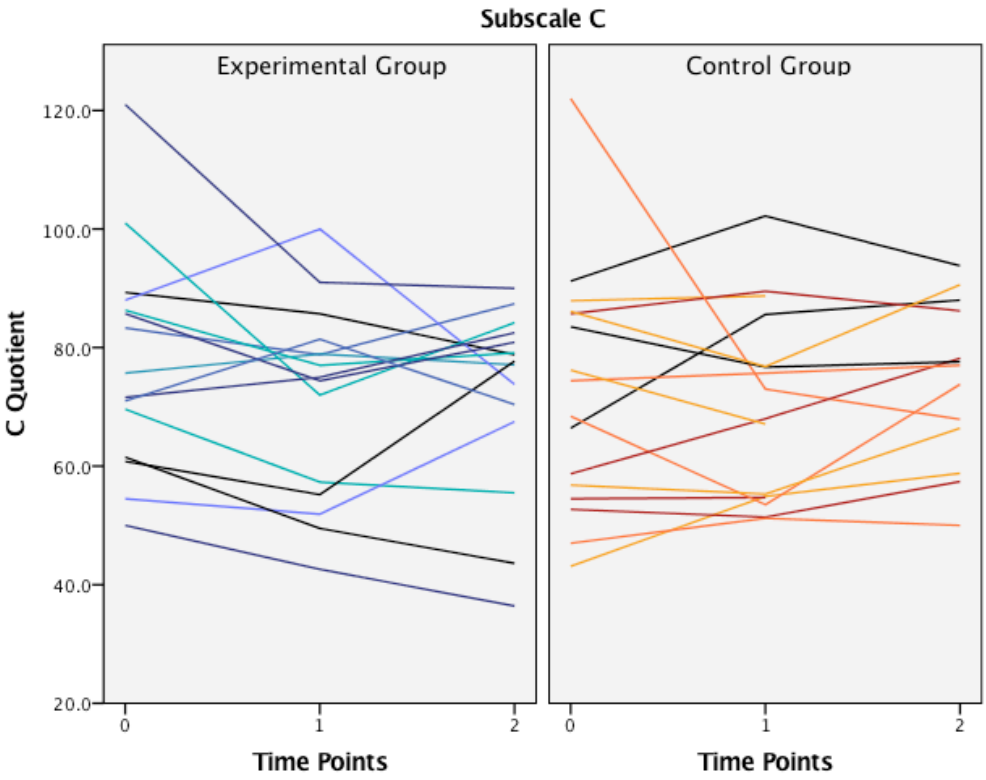

Figure 18: Spaghetti plot graph of language subscale (C) quotient in both groups over three time points

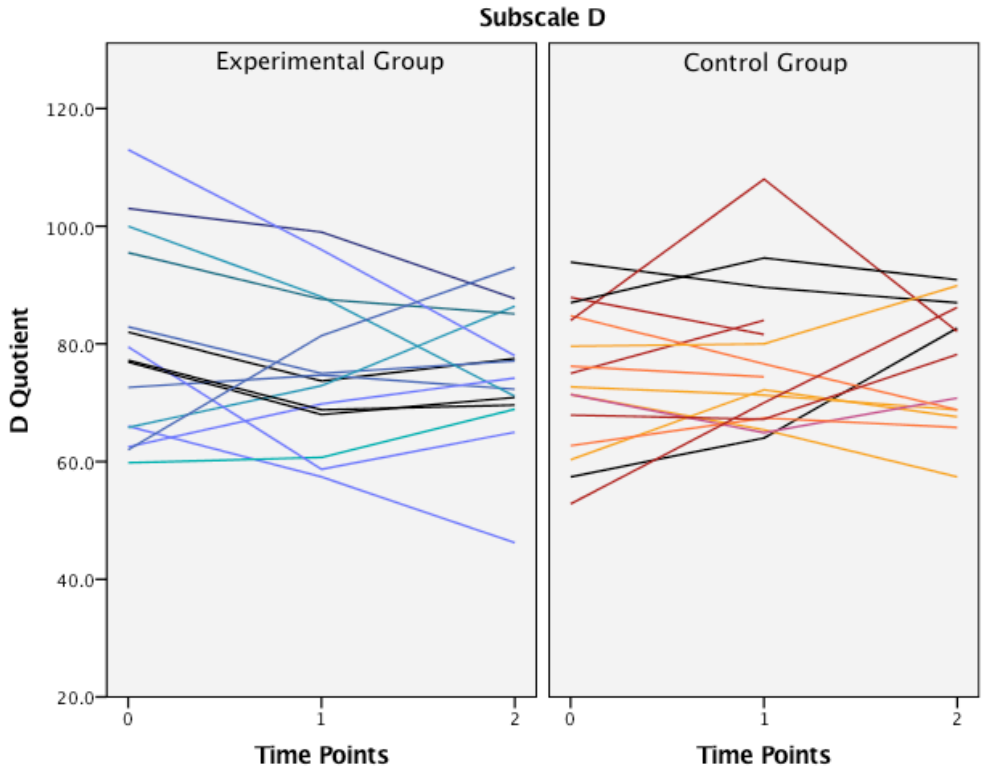

Figure 19: Spaghetti plot graph of eye-hand coordination subscale (D) quotient in both groups over three time points

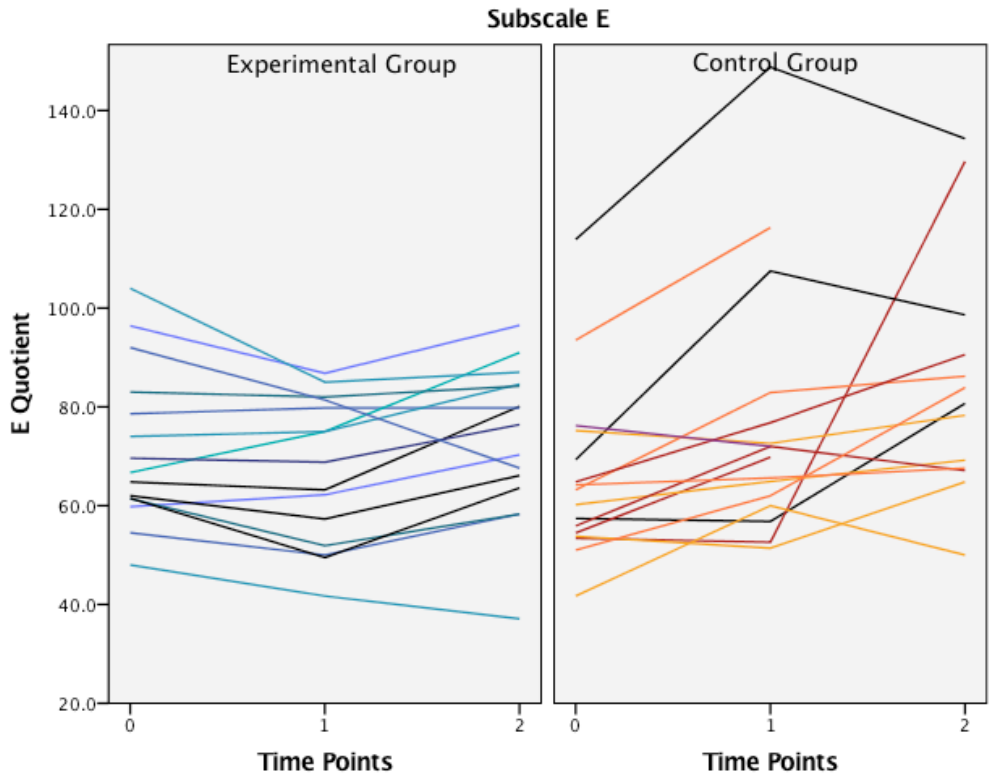

Figure 20: Spaghetti plot graph of performance subscale (E) quotient in both groups over three time points

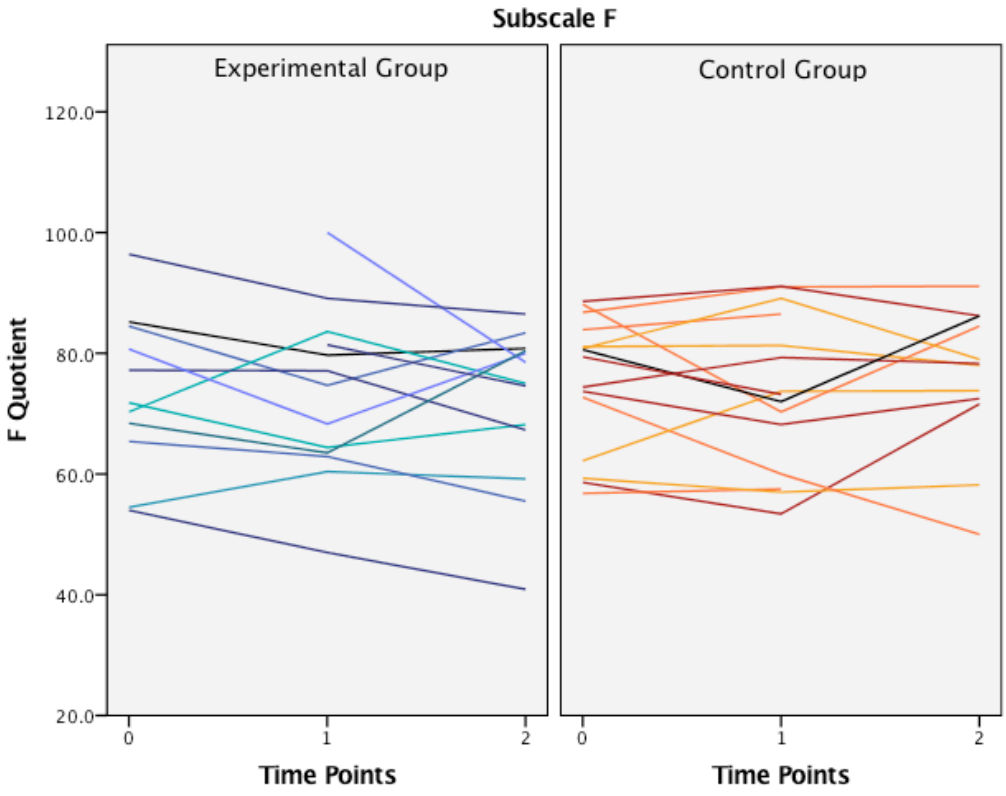

Figure 21: Spaghetti plot graph of practical reasoning subscale (F) quotient in both groups over three time points

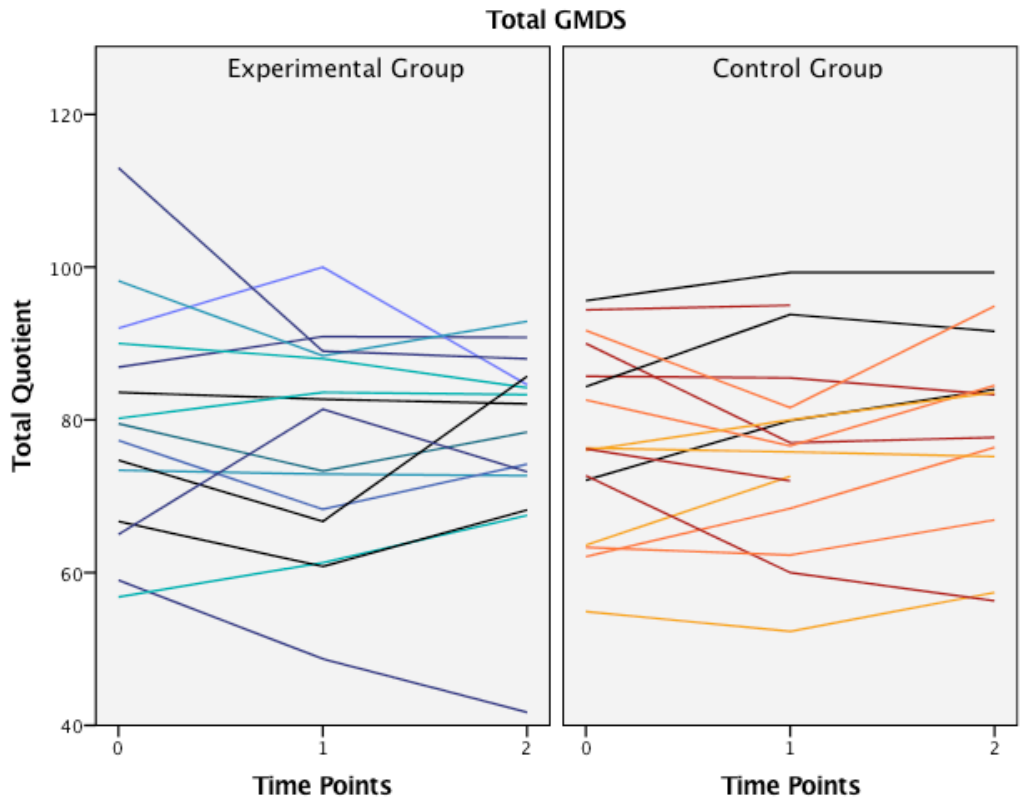

Figure 22: Spaghetti plot graph of total GMDS quotient in both groups over three time points

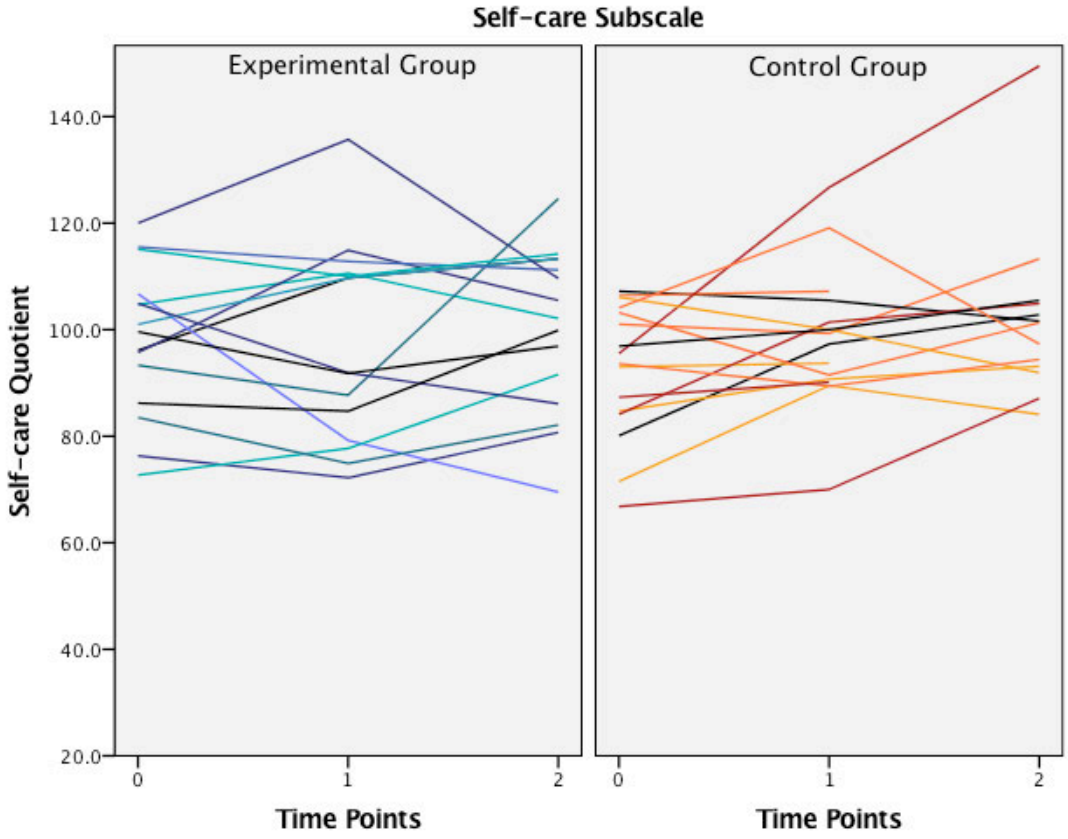

Figure 23: Spaghetti plot graph of self-care quotient in both groups over three time points

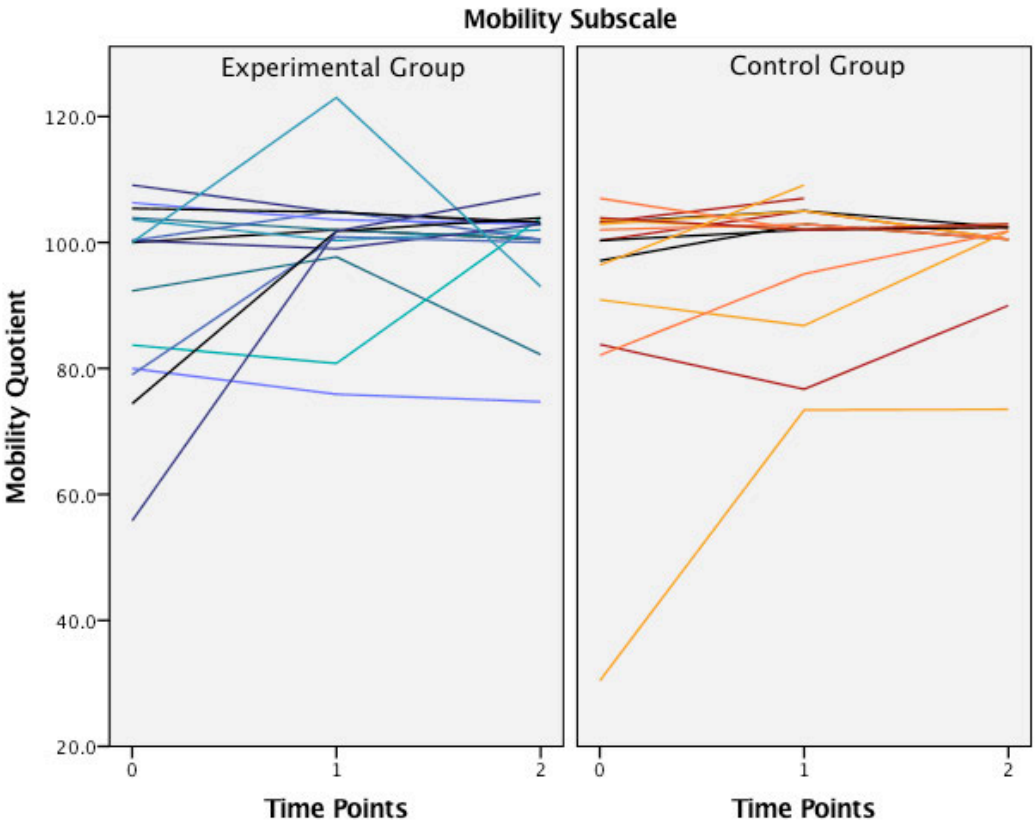

Figure 24: Spaghetti plot graph of mobility quotient in both groups over three time points

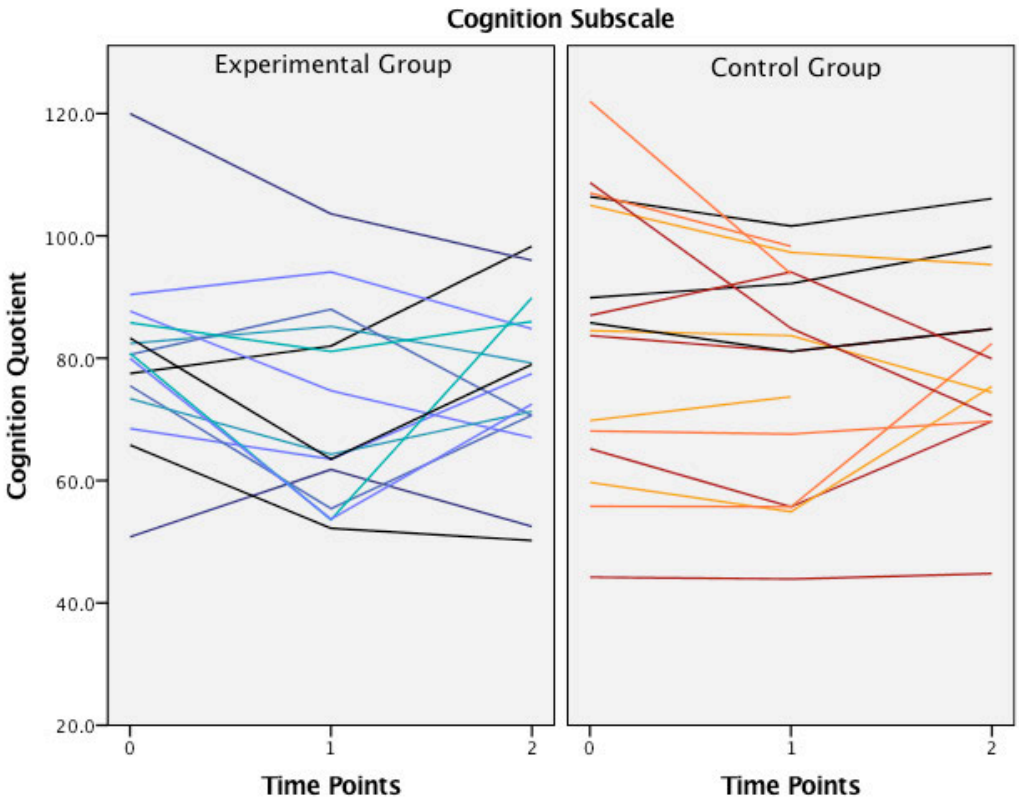

Figure 25: Spaghetti plot graph of cognition quotient in both groups over three time points

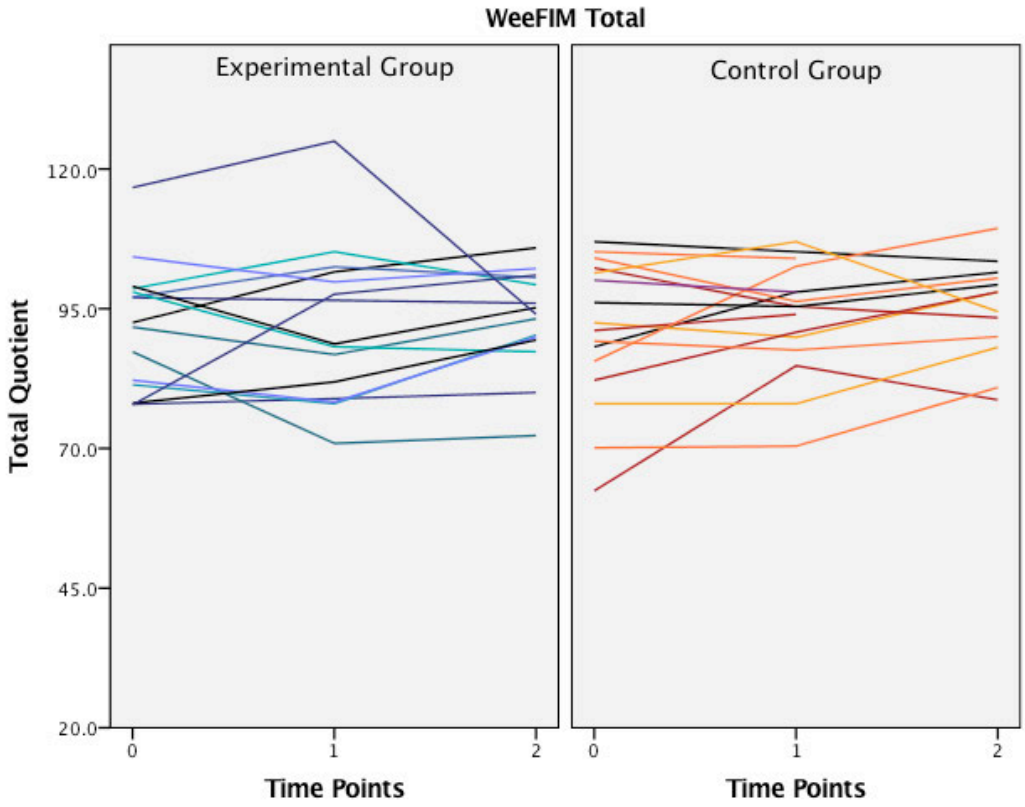

Figure 26: Spaghetti plot graph of total WeeFIM quotient in both groups over three time points

Table 12 indicates the differences between the GMDS mean scores (raw and quotient) from the baseline to post-test scores.

Table 12: Mean differences from baseline to post test scores

	GMDS													WeeFIM	
	Total raw	Total quot.	A raw	A quot.	B raw	B quot.	C raw	C quot.	D raw	D quot.	E raw	E quot.	F raw	F quot.	Total raw	Total quot.
Control mean difference	18.90	1.83	17.97	3.88	16.35	0.63	21.69	2.28	19.04	3.87	19.04	*21.31	19.32	0.21	13.00	5.90
Experimental mean difference	14.83	-1.92	18.95	0.47	15.92	2.14	14.79	-5.63	12.11	-5.05	13.92	1.64	13.43	-2.84	18.33	1.13

GMDS Raw scores (and F quotient): control n=12, experimental n=11
GMDS Quotients (except F) and WeeFIM: control n=13, experimental n=15
Differences in sample numbers occur due to the GMDS 0-2 and GMDS-ER 2-8 having different methods for calculating raw scores, those in GMDS 0-2 or mixture of both versions over baseline to post-test were excluded from the raw scores in this table.
*This data set appeared to have an outlier in that the difference from baseline to post-test quotient for one child was unusually high. If this data point is excluded from the set the mean quotient difference is 16.73 and the raw score difference is 16.95

Overall the quotient differences improved or decreased by a small number (range -5.63 to 16.73). The experimental group showed a decrease in quotient scores for total and language, eye-hand coordination and practical reasoning subscales (C, D, F). The raw scores all improved by a larger amount, indicating children did score more items over time. These improvements were not always enough to affect their quotient scores, as they also grew older over time.

Table 13 shows the number of children in each group that showed a positive difference between their baseline and post-test scores. These are the number of children that improved on their results.

Table 13: Number of children with positive differences from baseline to post-test scores

	GMDS														WeeFIM	
	Total raw	Total quot.	A raw	A quot.	B raw	B quot.	C raw	C quot.	D raw	D quot.	E raw	E quot.	F raw	F quot.	Total raw	Total quot.
Control	12	9	12	6	12	8	12	10	12	7	12	13	12	5	10	8
	100%	69.2%	100%	46.2%	100%	61.5%	100%	76.9%	100%	53.8%	100%	100%	100%	38.5%	76.9%	61.5%
Experimental	10	6	10	8	10	9	10	5	10	4	11	10	10	3	15	8
	90.9%	40%	90.9%	53.3%	90.9%	60%	90.9%	33.3%	90.9%	26.7%	100%	66.6%	90.9%	20%	100%	53.3%

GMDS Raw scores (and F quotient): control n=12, experimental n=11
GMDS Quotients (except F) and WeeFIM: control n=13, experimental n=15
Differences in sample numbers occur due to the GMDS 0-2 and GMDS-ER 2-8 having different methods for calculating raw scores, those in GMDS 0-2 or mixture of both versions over baseline to post-test were excluded from the raw scores in this table.

Table 14 portrays the changes in the numbers of children scoring <-2 z-scores (i.e. those children with a significant degree of developmental delay or learning disability on each subscale).

Table 14: Number of children with a z-score <-2

	Baseline Control n=12		Mid Control n=12		Post Control n=13	
Subscale A	5	41.7%	3	25.0%	3	23.1%
Subscale B	1	8.3%	2	16.7%	1	7.7%
Subscale C	7	58.3%	6	50.0%	6	46.2%
Subscale D	8	66.7%	9	75.0%	9	69.2%
Subscale E	9	75.0%	6	50.0%	6	46.2%
Subscale F	4	33.3%	5	41.7%	7	53.8%
Total GMDS	7	58.3%	9	75.0%	6	46.2%
	Baseline Experimental n=11		Mid Experimental n=13		Post Experimental n=14	
Subscale A	3	27.3%	5	38.5%	4	28.6%
Subscale B	0	0.0%	1	7.7%	1	7.1%
Subscale C	5	45.5%	6	46.2%	5	35.7%
Subscale D	4	36.4%	9	69.2%	10	71.4%
Subscale E	9	81.8%	9	69.2%	7	50.0%
Subscale F	6	54.5%	7	53.8%	6	42.9%
Total GMDS	8	72.7%	9	69.2%	9	64.3%

The control group had notably decreased numbers of children in locomotor and performance subscales (A and E) and a notable increase in numbers in practical reasoning subscale (F) from baseline to post-test assessment. The experimental group had notably decreased numbers of children in performance subscale (E) and notably increased numbers in eye-hand coordination subscale (D).

The tables below (Tables 15 to 17) show the significance of change in related quotient scores over two time points using the Wilcoxon Signed Rank test. The time intervals investigated were:

1. Baseline to mid-test,

2. Mid-test to post-test, and

3. Baseline to post-test.

($p \leq 0.05$, at 95% CI, highlighted in yellow, is deemed to be significantly different)

Table 15: Significance of changes in GMDS total quotients over three time points

	p-value		
	GMDS total		
	1	2	3
Control	0.600	0.050	0.221
Experimental	0.222	0.955	0.649

1 – baseline to mid-test comparison; 2 – mid- to post-test comparison; 3 – baseline to post-test comparison

Table 16: Significance of changes in GMDS subscale quotients over three time points

	p-value								
	Subscale A			Subscale B			Subscale C		
	1	2	3	1	2	3	1	2	3
Control	0.807	0.311	0.753	0.363	0.116	0.917	0.807	0.116	0.087
Experimental	0.191	0.172	0.865	0.910	0.570	0.410	0.050	0.609	0.125

	p-value								
	Subscale D			Subscale E			Subscale F		
	1	2	3	1	2	3	1	2	3
Control	0.345	0.861	0.442	0.019	0.196	0.001	0.530	0.583	0.638
Experimental	0.053	0.865	0.256	0.033	0.016	0.363	0.131	0.552	0.285

Table 17: Significance of changes in WeeFIM total quotients over three time points

	p-value		
	WeeFIM total		
	1	2	3
Control	0.433	0.116	0.075
Experimental	0.955	0.112	0.589

The control group had significant ($p \leq 0.05$) positive changes over time in their total GMDS scores mid- to post-test, and in performance subscale (E) baseline to mid-test and baseline to post-test.

The experimental group had significant ($p \leq 0.05$) negative changes over time in their language subscale (C) scores baseline to mid-test, and performance subscale (E) baseline to mid-test. They however showed a positive change over time in performance subscale (E) mid- to post-test.

Dosage

Each participant was supposed to attend ten intervention sessions. Of the total sessions that could have been attended (n=28x10=280), 43% (n=121) of sessions were not attended.

Table 18: Session attendance numbers

Attendance	Session number										Total	%
	1	2	3	4	5	6	7	8	9	10		
No	9	10	11	17	8	15	15	10	13	13	121	43.2%
Yes	17	14	14	9	18	7	13	16	14	13	135	48.2%
Partial	2	4	2	2	2	5	0	2	1	2	22	7.9%
Caregiver only	0	0	1	0	0	1	0	0	0	0	2	0.7%

Table 19: Reasons given for not attending a session

Reason	Session number										Total	%
	1	2	3	4	5	6	7	8	9	10		
Not stated	4	2	6	7	3	5	4	5	9	1	46	38.0%
Not stated but noted not a doctor consult date	4	4	3	6	4	8	5	4	1	10	49	40.5%
Child was sick	0	1	1	0	0	0	1	0	0	0	3	2.5%
Caregiver was working	0	1	0	1	0	0	0	0	0	1	3	2.5%
Away	0	1	0	2	0	1	2	0	1	1	8	6.6%
Apologies sent/excused	1	1	0	1	1	1	1	1	1	0	8	6.6%
Arrived too late	0	0	0	0	0	0	2	0	0	0	2	1.7%
Caregiver was sick	0	0	1	0	0	0	0	0	1	0	2	1.7%

The most common reason noted for not attending a session, was that on these days the child did not have a doctor's appointment (40.5% of the unattended sessions). This was not always explicitly stated by the caregiver, but noted by the therapists providing the interventions.

The average attendance over the whole study period was 5.4 sessions by the control group and 5.2 sessions by the experimental. The control group ranged from 1.5 sessions to 9 sessions; the experimental ranged from 2 sessions to 8.5 sessions. Participants were credited with 0.5 attendance if they only partially attended a session.

Table 20 shows the mean attendance for each intervention period. First and second intervention periods had a maximum of five sessions that could be attended while the total session attendance was a maximum of ten sessions.

Table 20: Mean attendance of sessions

	1st intervention period (max. 5 sessions)		2nd intervention period (max. 5 sessions)		Total session attendance (max. 10 sessions)	
	Mean (min-max)	SD	Mean (min-max)	SD	Mean (min-max)	SD
Control Group	2.5 (0-4)	1.2	2.8 (0-5)	1.8	5.4 (1.5-9)	2.6
Experimental Group	3.1 (0-5)	1.3	2.1 (0.5-5)	1.4	5.2 (2-8.5)	2.2

Figures 27-29 display the range, mean and standard deviations of attendance of sessions.

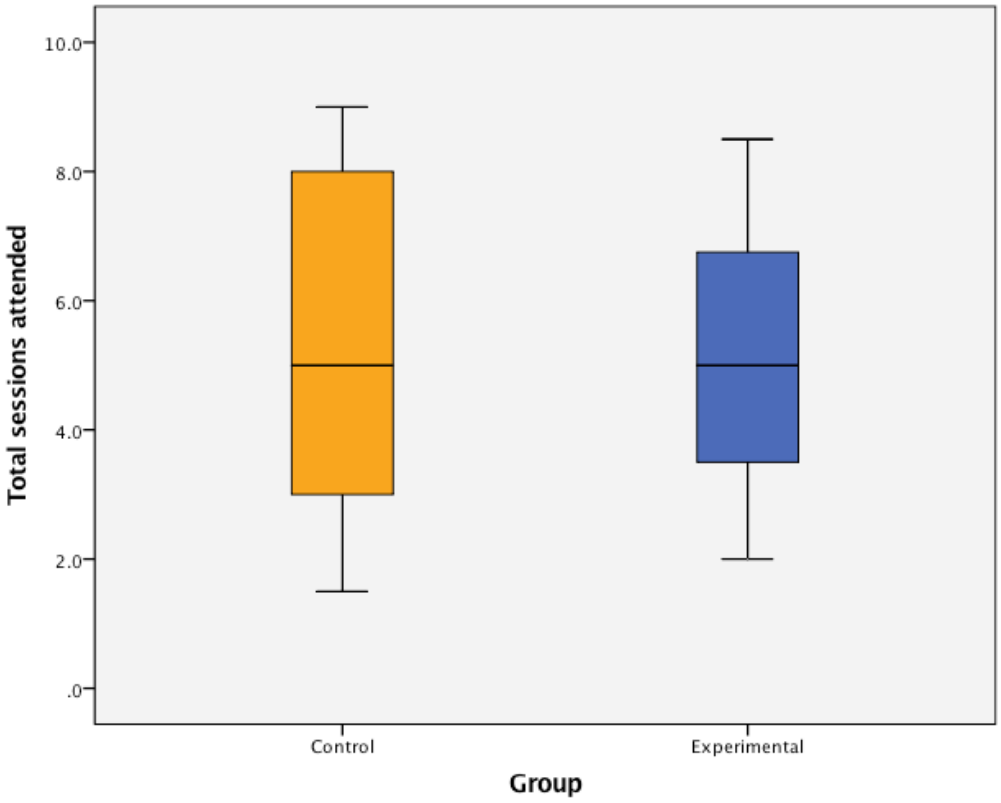

Figure 27: Box and Whisker plots of total sessions attended

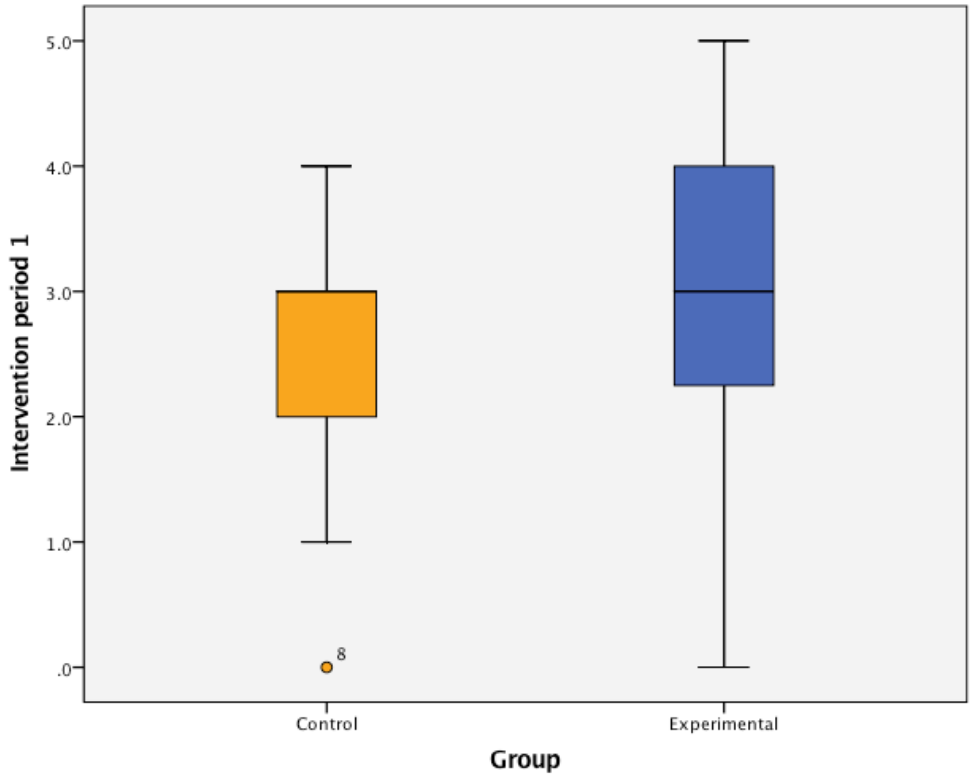

Figure 28: Box and Whisker plots of attendance of the first intervention period

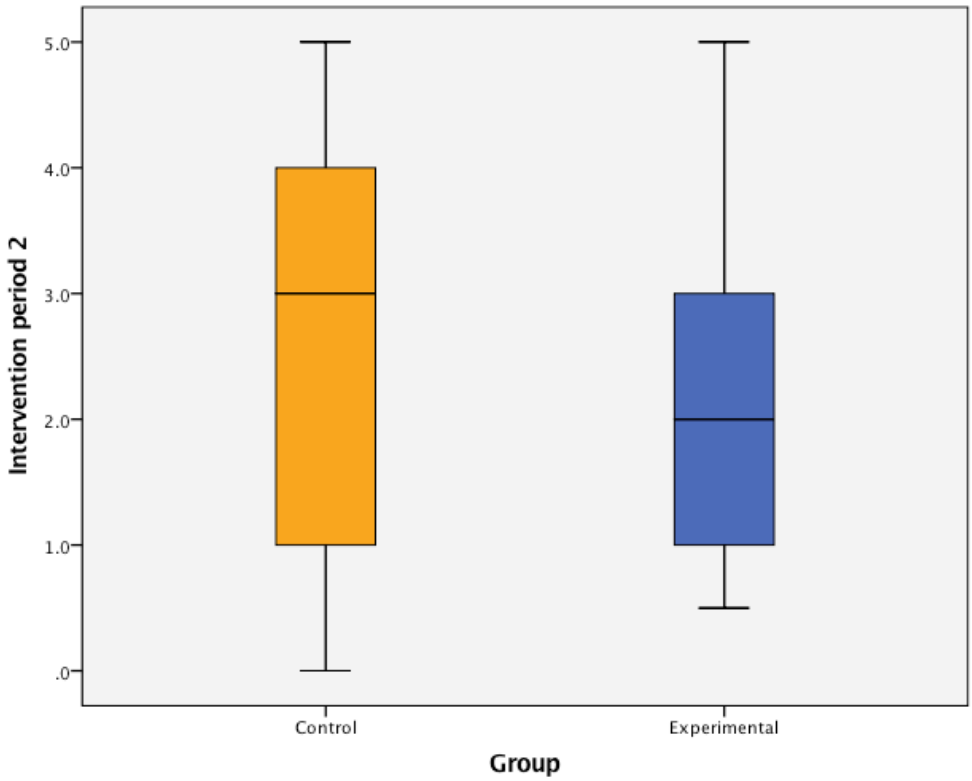

Figure 29: Box and Whisker plots of attendance of the second intervention period

There was a non-significant, weak, negative correlation between the total number of sessions attended and the total GMDS quotient score at post-test (Spearman's correlation coefficient -0.189, p=0.336). The sample size (n=28) was not big enough to provide the significance to definitively see a linear relationship between these two variables.

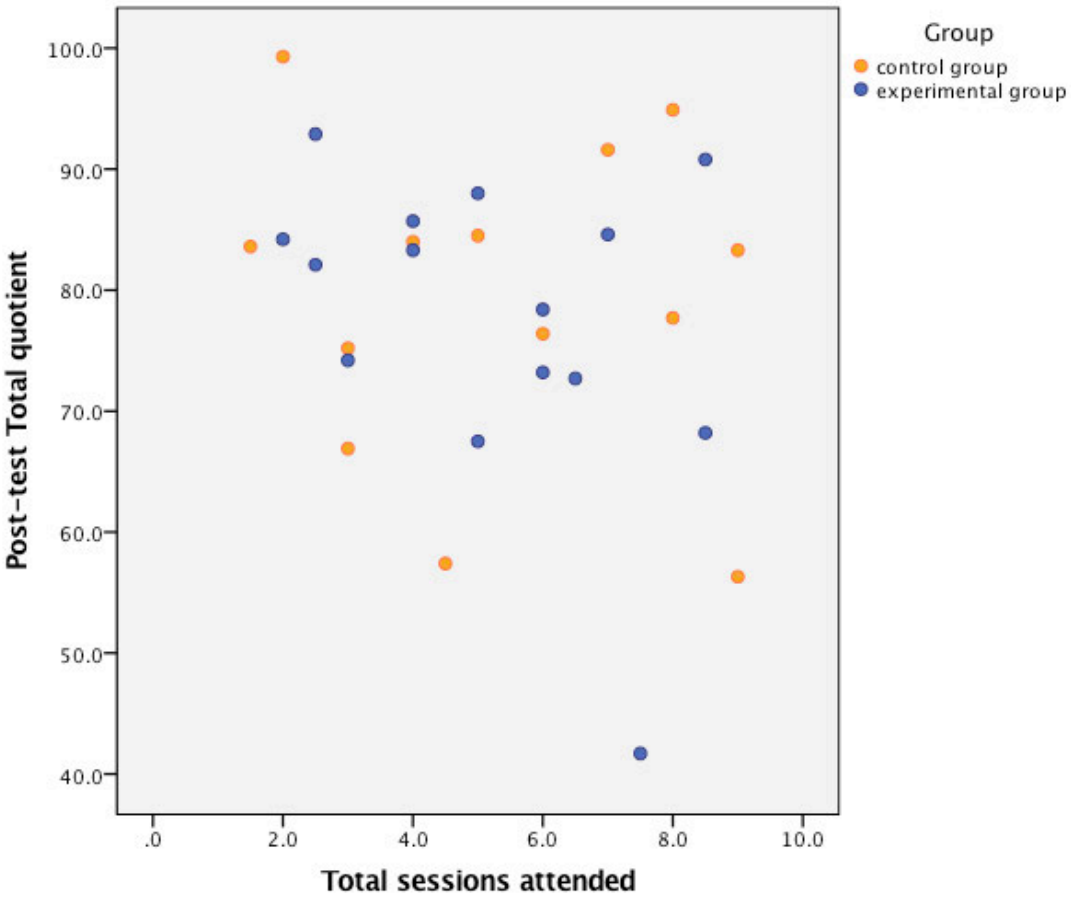

Figure 30: Scatter plot showing the correlation between Post-test total quotient scores and total sessions attended

Mixed Model Analysis

In addition to non-parametric tests performed a mixed model and random effects analysis was done to confirm and explore the results further. The mixed model analysis focuses more on the changes of trajectories in the participants (Kielhofner, 2006) and allows one to consider a variety of random subject-specific effects in addition to the population-average (fixed) effects.

Dosage of intervention, school exposure (if the participant had attended any sort of schooling environment during any time over the study period) and unsuppressed viral load at baseline were considered as random, subject-specific effects and incorporated into the

model. As missing data is not a problem for this analysis, all participants were included in this analysis, including those that did not complete mid- and/or post-tests (n=39).

Various models were tried in order to determine which yielded the best fit with the data. Initially, a model was tried incorporating the three time points. However, this model assumed the data line retained the same slope when moving through the three data points. Hence a more flexible model was tried with two data points (baseline and post-test), which didn't hold any assumptions about the slope.

As the sample size was small, an attempt was made to keep the number of parameters to a minimum. The sample size was not highly powered to detect differences. **Significance was determined as a p-value of less than 0.1 for the mixed model analysis.**

Model 1:

- Baseline to post-test (in attempt to reduce the number of model parameters, no assumptions about slope of data)
- Dose: was entered as dichotomous - the total number of sessions for each participant was coded to be either "yes" meaning they attended five or more intervention sessions; or "no" meaning they attended less than five sessions.
- **Viral load suppression (or rather lack thereof at baseline) and school exposure were included as the main effects in this model.**

This model picked up some results in subscales having been significantly affected by an unsuppressed viral load or school exposure. The analysis was repeated on these subscales using a model with only the significant effect in place (Models 1A and 1B). If the subscale showed no significance with these effects, the analysis was repeated with a model using none of these variables as an effect (Model 1C).

Model 1A:

- Baseline to post-test (in attempt to reduce the number of model parameters, no assumptions about slope of data)
- Dose: was entered as dichotomous - the total number of sessions for each participant was coded to be either "yes" meaning they attended five or more intervention sessions; or "no" meaning they attended less than five sessions.
- **Unsuppressed viral load (at baseline) was included as the main effect in this model.**

Model 1B:

- Baseline to post-test (in attempt to reduce the number of model parameters, no assumptions about slope of data)
- Dose: was entered as dichotomous - the total number of sessions for each participant was coded to be either "yes" meaning they attended five or more intervention sessions; or "no" meaning they attended less than five sessions.
- **School exposure was included as the main effect in this model.**

Model 1C:

- Baseline to post-test (in attempt to reduce the number of model parameters, no assumptions about slope of data)
- Dose: was entered as dichotomous - the total number of sessions for each participant was coded to be either "yes" meaning they attended five or more intervention sessions; or "no" meaning they attended less than five sessions.
- **No additional effects were included as the main effects in this model.**

Table 21: Models used for quotient scores

Subscale	Model used
Subscale A	1A
Subscale B	1B
Subscale C	1C
Subscale D*	1C
Subscale E	1C
Subscale F	1C
Total GMDS	1C
Self-care subscale	1A
Mobility subscale	1C
Cognition subscale	1B
Total WeeFIM	1C

*Subscale D originally showed a significant school exposure effect (p=0.066). However, when model 1B was run again the value was not significant anymore (p=0.109). Thus, model 1C was instead used to analyse this subscale.

Model diagnostics were performed to check for model misfit. This was done by plotting the residuals against the fitted values (see appendix L for the plots). All the model fits were adequate, with the residuals showing no clear trend or change in variability as the fitted value changed.

Table 22 shows the results from the mixed model and random effects analysis (significance, $p \leq 0.1$, is highlighted in yellow):

Table 22: Results from mixed model and random effects analysis

		Estimate (95% Confidence Interval lowerbound-upperbound) p-value			
Subscale	Model used	Difference in change (base-post) from control to experimental with FEW sessions attended (<5)	Difference in change (base-post) from control to experimental with MORE sessions attended (≥5)	Unsuppressed viral load	School exposure
A	1A	11.35 (-7.58 - 30.29) 0.232	-13.91 (-30.44 - 2.62) 0.097	-15.49 (-29.55 - -1.43) 0.032	
B	1B	-1.69 (-16.49 - 13.10) 0.818	8.27 (-4.86 - 21.40) 0.209		11.42 (-0.29 - 23.14) 0.056
C	1C	-3.17 (-19.55 - 13.20) 0.697	-6.26 (-20.55 - 8.04) 0.381		
D	1C	-6.52 (-22.89 - 9.85) 0.427	-2.47 (-16.76 - 11.82) 0.730		
E	1C	-5.62 (-22.34 - 11.09) 0.499	-24.93 (-39.52 - -10.34) 0.001		
F	1C	0.04 (-9.71 - 9.80) 0.993	-5.68 (-14.70 - 3.34) 0.208		
GMDS Total	1C	-2.31 (-12.63 - 8.02) 0.652	-3.45 (-12.46 - 5.56) 0.441		
Self-care	1A	2.79 (-16.81 - 22.38) 0.774	-11.56 (-28.67 - 5.55) 0.178	12.22 (-0.38 - 24.82) 0.057	
Mobility	1C	-1.69 (-16.43 - 13.05) 0.819	0.96 (-11.90 - 13.83) 0.881		
Cognition	1B	-5.36 (-19.54 - 8.81) 0.446	2.10 (-10.46 - 14.66) 0.735		13.01 (1.26 - 24.75) 0.031
WeeFIM Total	1C	-2.52 (-14.18 - 9.13) 0.664	-3.81 (-13.98 - 6.37) 0.454		

No significance was found between the control and experimental groups when they had attended few sessions (<5). However, locomotor (A), practical reasoning (F) and self-care subscale estimates indicate that the experimental scores increased more than the control.

Locomotor and performance subscales (A and E) were found to have significant control group score increases over the experimental group when more sessions were attended (≥5). No significance was found between the groups in any of the other subscales. However, personal-social (B), mobility and cognition subscale estimates indicate that the experimental scores increased more than the control.

Having an unsuppressed viral load had a significant negative effect in locomotor subscale (A), and a significant positive effect in the self-care subscale. Having had school exposure had a significant positive effect on personal-social (B) and cognition subscales.

Harms

No adverse effects were reported in either group for the duration of the interventions.

Chapter 4: DISCUSSION

Introduction

In this chapter the results of the study are discussed, briefly according to the overall aim and in depth with regard to the specific objectives and in the light of the literature. The discussion is presented in the same order and under the same sub-headings as the preceding sections. The ancillary results are also further discussed. These ancillary analyses are important as they bring additional depth to the study and draw attention to potential further studies and recommendations arising from this study.

The overall aim of the study was to investigate development in a cohort of HIV positive children on ART, and evaluate whether a PICIHBI experimental intervention facilitated by occupational therapists through clinic-based groups with caregivers, yielded a similar impact on the children's developmental outcomes, compared with a control of standard one-on-one occupational therapy intervention or not. This aim was met in that the data and analysis of results show that both interventions yielded similar results in general, and the PICIHBI intervention was not inferior, nor superior to that of the conventional intervention provided to the control group. There were some specific and subtle differences between the two groups with respect to specific subscales and these are discussed where appropriate below.

Objective 1 (Baseline developmental status)

Total GMDS scores

The GMDS average quotient scores of the total sample at baseline (78.7, table 6) indicates the sample's development is below average for their age and categorised as borderline mental retardation according to the UK interpretation categories (GMDS training course October/November 2012, Dr L. Jacklin). Reasons for low scores could be based on the following characteristics of the sample: positive HIV status, other medical diagnoses, low socioeconomic environment, quality of child-care and parenting skills, or lack of rehabilitation services.

Ten children had additional diagnoses that may have contributed to a low score. These diagnoses (HIVE, CP, history of otitis media, failure to thrive, prenatal drug exposure and epilepsy) are known to have negative effects on development. Four of these children had

an official HIVE diagnosis – a directly HIV linked diagnosis the impact of which on child development is discussed earlier (see 'Problem statement'); the remaining 6 had diagnoses not specifically linked to an HIV-positive diagnosis. Still, 8 (28.6%) children, who were without additional diagnoses (of those older than 2 years), had a total GMDS z-score lower than -2, indicating a degree of developmental delay or learning disability.

- *Comparisons with other South African samples:*

In comparison with other studies exploring the development of South African samples, with no known medical conditions, using the GMDS, the current study's sample performed lower on the GMDS at baseline assessment (a mean quotient of 78.7). Van Rooyen (2005) found their sample of South African children's (n=129, ages 4-7 years) overall performance quotient to be 113.36 on the GMDS. Van Rooyen's score was not significantly different to the British standardisation sample. Van Heerden (2007) and Jakins' (2009) South African samples scored total average GMDS quotients of 113 (n=31, 5-7 years old) and 116 (n=64, 5-7 years old) respectively. All three of these studies weren't truly representative of the larger South African population (despite attempts), and thus their results should be carefully considered. However, the current study's total GMDS average score at baseline is still considered low, even while bearing this in mind.

- *Comparisons with other HIV-positive samples:*

In comparison with other studies exploring the functioning of HIV-positive South African samples using the GMDS, the current study's percentage of children scoring a z-score of below -2 was higher (65.2%) than that of a recent study by Potterton, Hilburn and Strehlau (2016) which reported the developmental status of HIV-positive (on ART) South African pre-school children (between 3-5 years old, n=68). In the Potterton *et al.* (2016) study, 55.9% of the children scored below -2. Compared to a study by Lowick, Sawry and Meyers (2012) reporting the developmental outcomes of a slightly older sample of HIV-positive (on ART) South African children (55-75 months old, n=30), delays, as determined by the total z-score, were a lower percentage in the current study (65.2%) than Lowick *et al.*'s (90%). This is also seen in total quotient scores, where the current study scored higher than Lowick *et al.*'s HIV-positive sample (a total quotient score of 70).

When the younger children of the current study's sample (6-22 months old, n=5) mean quotient scores were compared with Laughton *et al.* (2012) sample of HIV-positive South African children (10-16 months old, n=64), the current study data shows lower quotient means in the total quotient.

The current study's total GMDS quotient and z-scores at baseline (table 6) seem to show mixed comparisons with other GMDS South African HIV-positive samples. This could be due to sample discrepancies or as Potterton *et al.* surmised, their differences to Lowick *et al.*'s results was due to earlier initiation on ART for their sample (mean of 8.1 months vs. 24 months) (Potterton, Hilburn & Strehlau, 2016). The current study's mean age when starting ART was 15.7 months, possibly explaining why the sample's performance was lower than Potterton *et al.*'s study but higher than Lowick *et al.*'s study. Ultimately, if this is the factor for differences in the results between these three studies, it reinforces Laughton *et al.*'s (2012) finding that early commencement on ART improves the neurodevelopmental outcomes of children.

The scores for HIV-positive South African children of all these studies were considered to be low when comparing them to the normative standards of the GMDS. The current data therefore aligns with the research indicating that even on ART, HIV-positive children's developmental scores are below normal levels (Smith, Adnams & Eley, 2010; Le Doaré, Bland & Newell, 2012; Lowick, Sawry & Meyers, 2012; Brahmbhatt *et al.*, 2014; Potterton, Hilburn & Strehlau, 2016).

- *Comparisons with other low socioeconomic samples:*

Both the Lowick *et al.* (2012) and Laughton *et al.* (2012) studies compared above additionally presented control samples of uninfected children of the same low socioeconomic status as their HIV-positive samples. Davies *et al.* (2011) also used a low socioeconomic South African control sample when exploring developmental delay in children with foetal alcohol spectrum disorder (FASD). When compared to the current study's results, all three control samples scored higher total quotients than the current study's sample. This indicates that HIV adds additional impact to development over and above socio-economic disadvantage.

GMDS Subscales

No concerns were raised in the personal-social subscale (B) in this study, however concerns of delay in the motor subscales (locomotor/A and eye-hand coordination/D) as well as language, performance and practical reasoning (C, E and F) were evident (table 6). The scoring pattern from highest mean quotient to lowest mean quotient was in the following order: personal-social, locomotor, eye-hand coordination, language, practical reasoning, and performance (B, A, D, C, F, and E). Language, performance and practical reasoning (C, E,

and F) subscales require verbal and cognitive skills and performance (subscale E) additionally requires visual-motor integration skills. Poor visual-motor integration may have also contributed to a low eye-hand coordination (subscale D) score (Pienaar, Barhorst & Twisk, 2014). (See appendix M for more details of the constructs used in each subscale.)

- *Comparisons with other South African samples:*

An analysis of the GMDS subscales revealed the underperformance of sample in the current study compared to 'normative' samples in studies conducted by Van Heerden (2007) and van Rooyen (2005). In these two studies the subscale quotient scores were all considered average scores. In the current study, all subscale quotient scores, with the exception of personal-social (B) were below average. Van Heerden had the following subscale pattern from highest to lowest: locomotor, personal-social, practical reasoning, language, performance and eye-hand coordination (A, B, F, C, E, D) and van Rooyen's was personal-social, locomotor, practical reasoning, language, eye-hand coordination, and performance (B, A, F, C, D, E). Their samples showed some similarities in the pattern of scoring when compared to the current study, namely locomotor and personal-social subscales (A and B) scoring the highest. The 'normative' samples had higher ordered practical reasoning (subscale F) but lower ordered eye-hand coordination (subscale D) when compared to the current study's pattern.

- *Comparisons with other HIV-positive samples:*

The current study and Potterton, Hilburn and Strehlau (2016) had similar results for the locomotor (subscale A) (34.8% and 32.4% delay, respectively) and language (subscale C) (52.2% and 54.4% delay, respectively). The current study had a lower percentage of <-2 z-scores for the personal-social subscale (B) and higher percentages of delay for eye-hand coordination, performance and practical reasoning (subscales D, E, and F). Potterton *et al.* (2016) noted that scales involving cognition and perception (language/C, performance/E and practical reasoning/F subscales) were more affected than motor skills subscales (locomotor/A and eye-hand coordination/D subscales). In the current study eye-hand coordination (subscale D) appeared to be one of the more affected subscales.

When compared to Lowick, Sawry and Meyers (2012), the current study yielded similar results in the degree of delay of eye-hand coordination (subscale D) (52.2% and 50% respectively). However, this study showed a more severe delay in performance (subscale E) (78.3% versus 63.3% respectively). The current study yielded higher mean quotients in locomotor, personal-social, language, performance and practical reasoning subscales (A, B, C, E and F). Lowick *et al.*'s quotient pattern from highest to lowest was: eye-hand

coordination, personal-social, locomotor, practical reasoning, performance and language (D, B, A, F, E, C).

Again, the current study's subscale results are varied when compared to other South African HIV-positive samples. The subscale scoring patterns do agree in that the more cognitive subscales (language/C, performance/E and practical reasoning/F) demonstrate worse results compared to scales involving motor skills. However, one of the differences noted is that the current study's eye-hand coordination (subscale D) scores were worse when compared to both Lowick *et al.* (2012) and Potterton *et al.*'s (2016) samples.

When the younger children's mean quotient scores in this study were compared with the Laughton *et al.* (2012) 10-16 months old HIV positive sample, lower quotient means in locomotor, eye-hand coordination and performance subscales (A, D, and E) were apparent. The results of the current study agree with data from other South African studies of HIV-positive children (Baillieu & Potterton, 2008; Potterton *et al.*, 2009) who also showed a higher motor delay than cognitive and language delays in younger samples (18-30months and 4-30months respectively).

- *Comparisons with other low socioeconomic samples:*

The comparisons between other low socioeconomic, South African samples indicated HIV's additional negative development effect across all developmental areas, beyond the low socioeconomic effects.

Kwesha's study (2009) gathered data on the developmental status of low socioeconomic South African children (between the ages of 24-60 months, n=16) using the GMDS subscales. The current study's sample scored lower in locomotor, personal-social, eye-hand coordination, performance, and practical reasoning subscales (A, B, D, E and F) (Subscale C scores were similar) compared to Kwesha's study. This may be an indication that HIV may contribute to lower developmental scores, although both studies have small sample sizes and thus this statement cannot be conclusively made. Kwesha's quotient pattern scores from highest to lowest were: locomotor, personal-social, performance, eye-hand coordination, practical reasoning and language (A, B, E, D, F, C) – performance rating a higher order and language rating a lower order than the current study.

Compared to Laughton *et al.*'s (2012) control (non-HIV) sample the younger children in the current study sample scored lower in all subscales (although with personal-social/B and language/C scoring fairly close to the control). The mean quotients of the current study are quite similar to the Lowick *et al.*'s (2012) control, except for eye-hand coordination and performance subscales (D and E) where the current study's scores are lower. Compared to

Davies *et al.*'s (2011) control sample, the current study's performance were all lower across all the subscales, with the largest differences noted in language and performance subscales (C and E). This supports the contention that HIV infection affects ECD beyond low socioeconomic affects.

Performance in locomotor subscale (A) in the current study aligned with Smith, Danoff and Parks (2002), Whitehead, Potterton and Coovadia (2013) as well as Ferguson and Jelsma's (2009) findings of low motor scores in children with HIV and taking ART.

Further GMDS subscale discussion

Personal-social (subscale B) was the only subscale in the current study to achieve average classification. This was the same finding as Potterton *et al.*'s (2016) recent study and Kotras' study (2001, unpublished thesis as cited in Jacklin & Cockcraft, 2013) on a similar HIV-positive South African sample. Van Rooyen (2005) found their 'normative' South African sample performed significantly better than the British sample in the personal-social (B) scores. This finding has however also been contradicted in other research where a British sample performed significantly higher in personal-social (B) compared to a 'black' South African sample (Amod, Cockcroft & Soellaart, 2007). The result of better personal-social (B) scores in South African children was attributed to the idea that South African parenting styles encourage quicker independence in self-care activities, possibly due to both parents working, suggesting children have to take responsibility of performing self-care tasks at a younger age (Van Rooyen, 2005). Similarly, Kotras (2001, unpublished thesis as cited in Jacklin & Cockcraft, 2013) suggests children in low socioeconomic environments develop more independence in self-care tasks as they are sometimes left with little or no supervision. Alternatively, this could be attributed to the parents' views and priorities – giving the children opportunity to learn to look after themselves early on. Due to South Africa's diversity and the close links of this occupational area with cultural and social values and routines (Shepherd, 2005) it is important to not forget these as affecting factors of independence in personal-social tasks. HIV may also be a contributing factor to better self-care and earlier independence especially in instances of single parents, orphans or sick caregivers. A study looking into children's care in a rural part of South Africa with a high HIV prevalence found 31% of orphans (including those with single parents) and 19% non-orphans were responsible for their own day-to-day care (Hill, Hosegood & Newell, 2008). Another study found children whose caregivers are sick with HIV/AIDS perform more household tasks and personal caregiving to their parent (Bauman *et al.*, 2006). Bauman *et al.* also found that their Zimbabwean sample was more likely to perform household and caregiving tasks as well as more regularly in comparison to their American sample.

The current data also aligns with other studies in stating performance in more cognitive domains (such as language/C, performance/E and practical reasoning/F) are lower than motor domain scores (Smith, Adnams & Eley, 2010; Potterton, Hilburn & Strehlau, 2016).

Overall, data in the current study are supported by other South African studies and concludes that HIV-positive children on ART are developmentally delayed and this delay extends across all motor, cognitive and language domains of their development.

The importance of considering low socioeconomic status with regards to South African GMDS scores is highlighted as integral according to Cockcroft, Amod and Soellaart (2008). Their study compared black South African children's GMDS performance and their mother's education level and profession – which were correlated with income. Those infants with professional, highly educated mothers performed significantly better on the GMDS than those with non-professional, less educated mothers (Cockcroft, Amod & Soellaart, 2008).

A study comparing GMDS scores of children with FASD – another disorder known to affect neurodevelopmental outcomes in children – and non-FASD children from the same community in South Africa found the scores of the FASD children lower than that of their counterparts (Davies *et al.*, 2011). However, the study's main discussion point centred around the fact that environmental factors could have a greater effect on a child's development with regards to a FASD child. Examples of these factors included: income, maternal education levels, quality of home environment, maternal health and depression, child's relationship with caregivers (also supported by Engle and Black (2007) and Walker *et al.* (2007)).

Maternal health and depression (which would in turn affect the quality of child care and the child's relationship with their mother) is particularly important when looking at HIV-positive mothers and their children's development (supported by Bass *et al.* (2016)). It is logical that a HIV-positive status and poor maternal health would have a larger compounding effect to the developmental status of a child in a low socioeconomic environment. HIV, not only affects the child directly, but also adds specific environmental effects over and above socioeconomic limitations.

From the discussion above, there certainly is some truth in suggesting that being HIV-positive puts low socioeconomic children at a greater risk for developmental delays. However, more research into this comparison would be valuable, before such a statement is accepted. Nevertheless, no matter what the cause may be of the low GMDS score, the data indicates a definite need for intervention to address development for this sample.

Objective 2 (Difference in GMDS total)

Differences between the total GMDS quotients of the experimental and control groups after intervention were not significant (table 8), indicating one intervention was not superior to the other.

The total mean difference between the control and experimental groups is within the predetermined non-inferiority margin of 6 points (difference of 3.75 points, table 12). This indicates that the experimental intervention is no worse than, or no better than the control intervention.

Some of the pros and cons of the control and experimental interventions have been outlined below (see 'Feedback from intervention therapists') but the fact that the two interventions have a similar impact is particularly relevant to rehabilitation services operating in resource poor settings, and/or with a massive load of children needing occupational therapy, such as in South Africa.

Objective 3 (Difference in GMDS subscales)

Differences between the individual subscale quotients of the experimental and control groups were not significant (table 9), indicating one intervention was not superior to the other with regard to any specific subscales.

The total mean difference between the control and experimental groups is within the predetermined non-inferiority margin of 6 points for locomotor (A) (difference of 3.41 points), personal-social (B) (difference of 1.51 points), and practical reasoning (F) (difference of 3.05 points) subscales (table 12). This indicates that the experimental intervention is no worse than or no better that the control intervention in these subscales.

However, language (C) (difference of 7.91 points), eye-hand coordination (D) (difference of 8.92 points) and performance (E) (difference of 19.63 points) subscales had differences greater than the non-inferiority margin on the negative side. This indicates inferiority of the experimental intervention in these subscale areas. Note, however, that while apparently 'inferior', these differences never achieved significance at the $p \leq 0.05$ level.

Also, it is important to note, superiority of the control cannot be assumed for these subscales, as the sample size is underpowered for a superiority trial (appendix N).

Different interventions yielded varied outcomes when considered as superiority trials. Potterton *et al.*'s (2010) intervention study saw significant improvements in cognitive and

motor aspects of the children's development, in the experimental intervention group. Boivin *et al.*'s (2013) intervention had a greater effect on language and cognition than motor skills. The current study appears to have mixed results - with gross motor and some cognition skills receiving non-inferiority while fine motor, language and other cognition skills did not perform as well as the control intervention. All these studies were comparing different interventions, which all had caregiver involvement, but were different in age group focus. The current study is the only study comparing two interventions, rather than a control of no intervention, and with a specific focus on occupational therapy intervention.

Changes over time

Following consultation with another GMDS researcher (Dr. B. Laughton) and through reading articles (Powell & Baker-Henningham, 2004; Laughton et al., 2010; Davies et al., 2011), it was expected that the GMDS quotients may decrease between the baseline assessments and post assessments in the study sample. Other studies mentioned below, also had this result with and without interventions. Hence the researcher did not interpret a slightly diminished total GMDS quotient in the experimental group over time (table 5) as a negative result. This may be due to how the quotient scores are calculated, as all the raw scores showed positive increases over time, but not enough to always affect the quotient. Laughton *et al.* (2010) also confirmed in their study (low socioeconomic, HIV-negative sample) that the younger children performed better on the GMDS, and a deceleration in development was noticed as the children got older.

In a year-long Jamaican malnutrition intervention study (children aged 9-30 months at beginning of trial)(Powell & Baker-Henningham, 2004), the average difference between the quotients of malnourished children receiving a developmental stimulation intervention was a negative difference of -6.1 between the two test intervals. Their control (malnourished children not receiving intervention) average quotient difference (test one to test two) was -12.9.

A South African study, measuring the longitudinal development of children with a low socioeconomic status (aged 10-12 months at the beginning of study) over two time points (10 months apart) (Laughton *et al.*, 2010), yielded an average difference between the quotients of -11.35.

In another South African study, measuring the development of FASD and non-FASD children (aged 7-12 months at beginning of study) in a low socioeconomic area over two time points (10-17 months) (Davies *et al.*, 2011), the average difference between quotients of non-

FASD children was -15.6. The FASD children's average quotient difference (test one to test two) was -22.7.

A similar pattern was seen in the results of the current study: GMDS quotients of the control group increased on average across the subscales by 4.9 points and the experimental group decreased on average by -1.6. The raw scores of the control group increased on average across the subscales by 18.9 points and the experimental group's average was an increase of 14.9 points across the subscales. This indicates that on average participants did score more items in the GMDS over time, but this was not always enough to increase their quotient scores. It should be noted that, compared to the two South African studies mentioned above that did not involve an intervention, the data of the current study showed better quotient differences over the two time points. This indicates that occupational therapy intervention is beneficial in this population.

For the control group: all GMDS raw scores increased from baseline to post-test results (increases ranged from 16.4 to 21.7 points over the subscales). The number of children scoring a z-score below -2 decreased in locomotor and performance subscales (A and E), but increased in practical reasoning subscale (F). Significant positive changes were noted in the total quotients (in the 2nd intervention period) and performance subscale (E) (over whole period). Significant differences were found in the mixed model analysis when more sessions were attended in locomotor and performance subscales (A and E).

For the experimental group: all GMDS raw scores increased from baseline to post-test results (increases ranged from 12.1 to 19). The number of children scoring a z-score below -2 decreased in performance subscale (E) but increased in eye-hand coordination subscale (D). Significant negative changes were noted in language, eye-hand coordination and performance subscales (C, D and E) over the 1st half of the intervention, however significant positive changes were noted over the 2nd intervention period for the performance subscale (E).

These results have clinical significance that should inform intervention changes in constructs/skills these subscales cover.

Objective 4 (Difference in WeeFIM total)

Differences between the WeeFIM total quotients of the experimental and control groups were not significant (table 10), indicating one intervention was not superior to the other with respect to this measurement tool.

The total mean difference between the control and experimental groups is within the predetermined non-inferiority margin of 6 points (difference of 4.77 points). This indicates that the experimental intervention is no worse than or no better that the control intervention.

Objective 5 (Correlation between GMDS subscale B and WeeFIM)

The WeeFIM has been proven to be reliable in detecting change in children with various disabilities and severities (such as Down's Syndrome, cerebral palsy, congenital impairments, developmental disorders, communication disorders and intellectual impairments) over time (Ottenbacher *et al.*, 2000; Wong, Au-Yeung & Law, 2005). It has also been found to correlate well with other functional and developmental assessments for children with developmental and physical disabilities (Ziviani *et al.*, 2001; Wong, Au-Yeung & Law, 2005; Grilli *et al.*, 2006).

The GMDS personal-social subscale (B) and the WeeFIM are purported to assess a child's functional independence especially in the area of self-care or activities of daily living (ADLs) according to what is expected at their age. The additional assessment of the WeeFIM was included in the study to complement the GMDS-ER data and build on the current paucity of data in the outcome area of self-care development in HIV-positive children. The two assessments' scores were correlated as the WeeFIM was found to have no published data on a South African sample.

The scores from the two assessments were significantly positively correlated (figure 15), therefore they do measure similar constructs. The WeeFIM could be an alternative assessment of self-care for occupational therapists.

It was noted that many of the children in this study achieved full independence in the mobility subscale of the WeeFIM assessment. A reason for this may be because the study's sample had few children with existing physical disabilities. A recent South African study also found some problems with the WeeFIM scores of their children (Scott, 2015), concluding that scores of children with chronic health conditions and without a physical disability may have ceiling affects. Although the WeeFIM can be an objective assessment, the suitability of this assessment to measure functional independence in children with chronic health conditions and without physical disability may be limited (Scott, 2015). Other studies have also noticed children seem to score higher in the mobility subscale than the self-care and cognition subscales (Wong, Au-Yeung & Law, 2005; Grilli *et al.*, 2006).

More research is needed on the use of the WeeFIM in a South African population. However, this study shows it is well correlated with the GMDS personal-social subscale (B), which is widely used and accepted in a South African setting across medical professions (physicians, psychologists and rehabilitation therapists).

School exposure correlation

In the mixed model analysis, school exposure was added as a main effect on developmental outcomes when analysing the scores (table 22). School exposure was defined as positive if the participant had attended any form of educational facility setting (crèche or school) during the study period. If the child was at home with their caregiver or a day mother, this was not considered as school exposure.

Two subscales were recognised as being significantly positively effected (at the $p<0.1$ level) by school exposure: GMDS personal-social (B) ($p=0.056$) and WeeFIM Cognition ($p=0.031$). Both these subscales have items relating to social interactions. That children attending a crèche or school would achieve higher scores in these subscales would make sense as they are exposed to a more social environment where they have the opportunity to practice and develop these skills.

Eye-hand coordination (subscale D) had a significant school exposure effect using the model 1 ($p=0.066$), however this significance decreased when model 1A was run ($p=0.107$). It is still important to note that school exposure had some effect on the subscale, even if it was not ultimately significant. Eye-hand coordination Subscale (D) contains many items assessing the child's ability to draw and reproduce forms, letters and numbers (emergent literacy skills).

From professional experience working in a low socioeconomic environment, the researcher has observed that these skills are often not stimulated at home at a young age and children only have the chance to develop and practice these skills when they start attending a school. This is confirmed by Sherry and Draper (2013) who reviewed research looking for the relationship between gross motor skill and school readiness in South African children. They summarised their findings of poor developmental skills in children due to lack of early experiences in general sensorimotor experiences (linked to later motor cognitive and perceptual skills) as well as experience with language and literacy materials namely, paper, pencils and books (Sherry & Draper, 2013). Their article also states that teachers in ECD centres in low socioeconomic areas, place more emphasis on teaching cognitive skills such

as counting and letters (Sherry & Draper, 2013). This could explain the effect of school exposures on the eye-hand coordination subscale.

Unsuppressed viral load correlation

In the mixed model analysis, an unsuppressed viral load was added as a main effect when analysing the scores (table 22). This was defined as a child having an unsuppressed viral load at the start of the study period.

GMDS Locomotor (A) ($p=0.032$) was recognised as having significant (at the $p<0.01$ level) unsuppressed viral load negative effects, while WeeFIM self-care ($p=0.057$) subscale had a significant unsuppressed viral load positive effect. Locomotor (A) involves many gross motor skills, whereas the self-care subscale involves more fine motor skills with some mobility. It is important to note that participants who had unsuppressed viral loads at the start of the study did not have additional diagnoses with physical impairments. It is also important to note that of those who had unsuppressed viral loads at the start of the study, only one continued to have an unsuppressed viral load at the end of the study, and there were other participants whose viral load became unsuppressed at the post-test. Laughton *et al.*'s (2012) study comparing deferred versus early ART initiation (in children aged 10-16 months old) found those that had not started ART had lower locomotor scores compared to those who were already on ART. However these samples did not have unsuppressed or significantly different viral loads (Laughton *et al.*, 2012). It is suspected that these significant results hold no meaningful conclusions and more research might be needed to investigate the effects of an unsuppressed viral load on child development.

Dosage

Both interventions were on average only attended approximately 50% of the time. Locomotor (A) and performance (E) in the control group were found to be significantly effected by the participants attending five or more of their intervention sessions (table 22).

The reasons for not attending sessions were sometimes recorded by the intervention occupational therapists. It was noted that 40.5% of those that did not attend and did not give an alternate reason, the session was on a day when they did not have a doctor's appointment. Unfortunately, reasons for not attending were not always followed-up on, so it cannot be conclusively stated, but it was assumed that 'not the same day as the doctor appointments' was the reason for not attending. The reason why participants could not

attend unless it was not on the same day as their doctor's appointment is not known. However, some of the reasons may be due to practical problems: occupational therapy appointments were not attended unless on the same day as the doctor because the caregiver/child could not get off work/school or money for transport was not available; or because of the opinion that therapy is not deemed important enough to warrant going to clinic.

As this study's clinic location was a tertiary hospital, many of the patients attending the clinic do not live in the immediate areas surrounding the hospital. They travel to the clinic from various areas in the Cape Town metropole up to about 25km away. Money toward transport reimbursement was a standard rate and not dependant on how far away their homes were. It was also only reimbursed at the clinic, meaning they had to have some money to get there in the first place. These reimbursement terms were aligned with the usual transport reimbursement provided to any patient attending the clinic. This factor could have affected attendance to the clinic and the interventions.

In Potterton *et al.*'s (2010) study time and cost constraints were kept in mind when designing the intervention. The intervention provided was aligned with the child's clinic appointments, which was only every three months. Khondowe *et al.*'s (2015) study followed-up participants every three months as well, however it is not mentioned if intervention was continued at these follow-ups or if the appointments were aligned to the participants' doctor appointments. Boivin *et al.*'s (2013) intervention took place monthly at the participant's homes.

It needs to be investigated further if attendance of occupational therapy would be better if it were provided at local ARV clinics, closer to the patient's homes. Alternatively, exploration would be needed to see if the intervention would have an effect if it were provided only at the same day as a doctor's appointment, with the condition that these are more likely to be spaced further apart (every two or three months not every month).

Feedback from intervention therapists

Feedback was gathered from the intervention therapists as to their experiences in organising and carrying out the two interventions. As this was not formally gathered and verbal in nature it is not included in the 'results' section. Nevertheless, it is useful and enlightening to consider their informal feedback as additional discussion.

Therapists found that trying to align the occupational therapy appointments with doctor and pharmacy appointments was challenging, as they did not always follow a particular monthly pattern.

Poor attendance was also noted even if the participant had a doctor appointment. Participants would then appear at the clinic on a later day without an appointment. If the participant was in the control group, this was easier to handle as the therapist could almost always make time to see them on that day. However, if the participant was in the experimental group, there was not always the correct age group session planned for that day, and they would have to reschedule another occupational therapy appointment.

The experimental intervention therapist also found it challenging to gather all the participants for a particular group together at the scheduled time. Many participants arrived late for their appointment, causing the therapist to have to catch them up on what they had missed but this was a quick review and not always to the same thoroughness.

If participants (control or experimental) arrived late at the hospital, this meant that there was less time to attend to all the other necessary appointments on the same day. Seeing the doctor, taking blood, receiving medication, seeing other professionals (counsellors, psychologist, dietician) and the free lunch (provided by the hospital clinic) were always prioritised over their occupational therapy appointment. The experimental intervention therapist noted that there seemed to be much more to get done at this particular clinic than at other clinics in different areas, implying the intervention may have a different response at a different clinic environment.

It was reported by all therapists that the low prioritisation of the occupational therapy session was not true for all participants. Caregivers that saw the value of attending occupational therapy were more committed to attend their appointments. This was often the case if the child had visible delays or difficulties that the caregiver was aware of. This was also difficult for the experimental intervention as those that did not see the benefit were reluctant to attend and participate in the group. The control intervention did not specify the caregiver to be in attendance for the therapy session. It is possible that caregivers who did not see the value, preferred this intervention as they could continue with other clinic tasks while the child attended the control intervention.

Other factors that the therapists reported as possibly having an effect on attendance were:

- Phone numbers regularly changing making it difficult to send reminders or rebook missed appointments.
- Transport reimbursements did not always cover the full cost of the trip to the clinic

- The control intervention therapist changed twice.
- The disruption of the December-January school holiday break.

Strengths and contributions of the study

The current study is the first randomised control trial study investigating the effectiveness of two different types of occupational therapy interventions on HIV-positive (on ART) children's development and provides valuable information for the occupational therapy profession in this domain of practice.

Strengths of the study included careful reporting according to the CONSORT statement (Moher et al., 2010), use of intension-to-treat analysis, and strict adherence to the conditions of a randomised control trial to ensure this was a well conducted trial. The study made use of tools that included subjective and objective measures to report child developmental outcomes.

The current study compared two interventions rather than no intervention, providing information to support what could be the better intervention in a resource constrained setting.

Study limitations

Although the sample size was highly powered to test for non-inferiority of the interventions, it was not large enough, thus not highly powered, to look into superiority of either intervention. Additionally, the sample was not large enough to provide generalizability for the descriptive baseline statistics to the larger South African population of HIV-positive children on ART.

This study did not factor in a way to record if the caregiver implemented any of their learning from the experimental sessions at home between appointments. Further investigation into this would provide valuable information with regards to dosage at home and caregiver outcome changes (if the interventions had any effects on caregivers knowledge, health, caregiving ability).

Although inter-rater reliability was established before the data collection took place. It was not formally assessed again, although it was monitored by methods described above in attempt to maintain reliability across the assessors throughout the study period.

Chapter 5: CONCLUSIONS AND RECOMMENDATIONS

The data presented in the current study leads to a conclusion that HIV-positive children (aged between 6 months and 5 years old), on ART need intervention to address concerns in their developmental occupations. The baseline results indicate that these children are developmentally delayed across all GMDS subscale areas except personal-social (subscale B).

The study set out to compare two occupational therapy interventions, and provide evidence for their ability to impact developmental scores this population. The data showed that overall, an experimental intervention (PICIHBI) and a control conventional occupational therapy intervention yield similar results and the experimental intervention is not inferior to the control.

There were specific subscale differences between the control and experimental groups with the control group preforming better in in GMDS language(C), eye-hand coordination (D) and performance (E) subscales. This provides important evidence to inform possible changes in the experimental intervention going forward.

Although the interventions have similar results and one is not inferior to the other, both have their merits. The experimental PICIHBI is group based and is thus able to reach more child-caregiver dyads. This is a critical consideration in the current South African context, where there is a lack of human resources. The logistics of organising group appointments was difficult in the clinic environment, and would need to be addressed if adopting a PICIHBI approach to therapy. Another pro for the experimental PICIHBI is that it is caregiver focused which may well provide more benefits than just child outcomes. The caregivers' relationship with the child as well as the group support effect may additionally improve caregiver health and wellbeing. In favour of the control intervention of one-on-one conventional occupational therapy is the possibility that the therapist may provide intervention that is more tailored to the child's specific needs and logistically easier to organise with the caregiver.

On average participants in both control and experimental groups scored more items in the GMDS over time (their raw scores increased), but this was not always enough to increase their GMDS quotient scores. Thus while neither therapy of ten sessions (over approximately 12 months) yielded statistically significant overall positive differences in total GMDS quotients between baseline and post-test intervals, the total quotient scores did not deteriorate significantly implying a positive outcome of therapy. Further, the quotient

differences between the baseline and post-test interval is sufficient to conclude that occupational therapy intervention is beneficial in this population.

The WeeFIM was identified as an alternative self-care measure for occupational therapists to use with children. However, the accessibility of the measure may be considered a limitation of its use within a South African environment. Research should be undertaken into what currently is being used by South African therapists, as well as standardised, accessible assessments for this outcome in children.

Completion of the study

As PICIHBI was found to have non-inferior outcome results, the intervention will continue to be rolled out to all clinic service users (including those who were in the control group), as it is a more efficient use of limited occupational therapy resources in a large HIV on ART population.

The results of the study are yet to be disseminated to stakeholders, including the Western Cape Department of Health through the Children and Families Directorate, other rehabilitation professionals and paediatricians through scientific meetings, the DG Murray Trust, the South African Medical Research Council, as well as peer-reviewed journals. The baseline results were presented at the 5th Conference of the International Society for Child Indicators conference in September 2015, together with the other co-researchers' baseline results. The researcher views further communication of the results of this study as critical and a necessary element of both the scientific process, and of responsible and engaged scholarship within the community.

Recommendations for practice

Although the study was not designed to delineate the impact or role of occupational therapy on developmental outcomes in HIV positive children *per se,* it is clear that the critical role that rehabilitation services may play in this population as outlined in the introduction (see 'Rationale for the study'), is supported by this study.

Further consideration around the dosage difficulties (i.e. how many sessions were attended) highlighted by the data is needed. Both control and experimental interventions showed difficulties in attendance of the interventions. Alternative options need to be explored. For example, should the PICIHBI syllabus be condensed into fewer sessions

covering more information per session, and aligned with doctors' appointments (bi/trimonthly) or should the current session plan be maintained, but aligned with doctors' appointments. In the latter case completion of the programme would necessarily be over a longer period. On the other hand, it is possible that attendance and dosage may produce different results in an alternative clinic environment (local clinic/community health centre). It would be prudent to entertain and explore this possibility before further adoption or adaptation of the intervention.

Content of PICIHBI needs to be revised particularly in constructs found in language, eye-hand coordination and performance subscales (C, D and E). These were the subscales that produced inferior results compared to control, conventional occupational therapy intervention. The constructs covered in these subscales (appendix M) need to be enhanced, highlighted and emphasised more in the PICIHBI session outlines. Additionally, current methods of educating and training the caregivers in these aspects may need to be reviewed.

Further research questions and studies

Areas needing further research and questions arising from this study are:

- What is the affect of unsuppressed viral loads on developmental outcomes in children?
- What is the influence of socioeconomic status in affecting the child development outcomes of HIV-positive children?
- The WeeFIM validity in South African populations needs to be assessed.
- Alternative paediatric self-care assessments and their use in South Africa should be investigated.
- The performance (possible superiority) of the interventions used in this study need to be assessed in a larger sample size.
- Is there a difference in performing the experimental intervention in other clinic environments such as more locally situated community clinics, health centres or other community NGOs?
- Further research into additional changes in caregivers (e.g. knowledge, health, self-esteem, caregiving ability, depression) involved in the experimental intervention should be assessed.

While it is always the case that one research study or element thereof raises further questions, the study undertaken is the first such and provides evidence that PICIHBI provides a good alternative to conventional occupational therapy in HIV-positive children (aged between 6 months and 5 years old) on ART as it reaches more dyads and could have additional benefits, within a limited resource setting, provided logistical difficulties are addressed.

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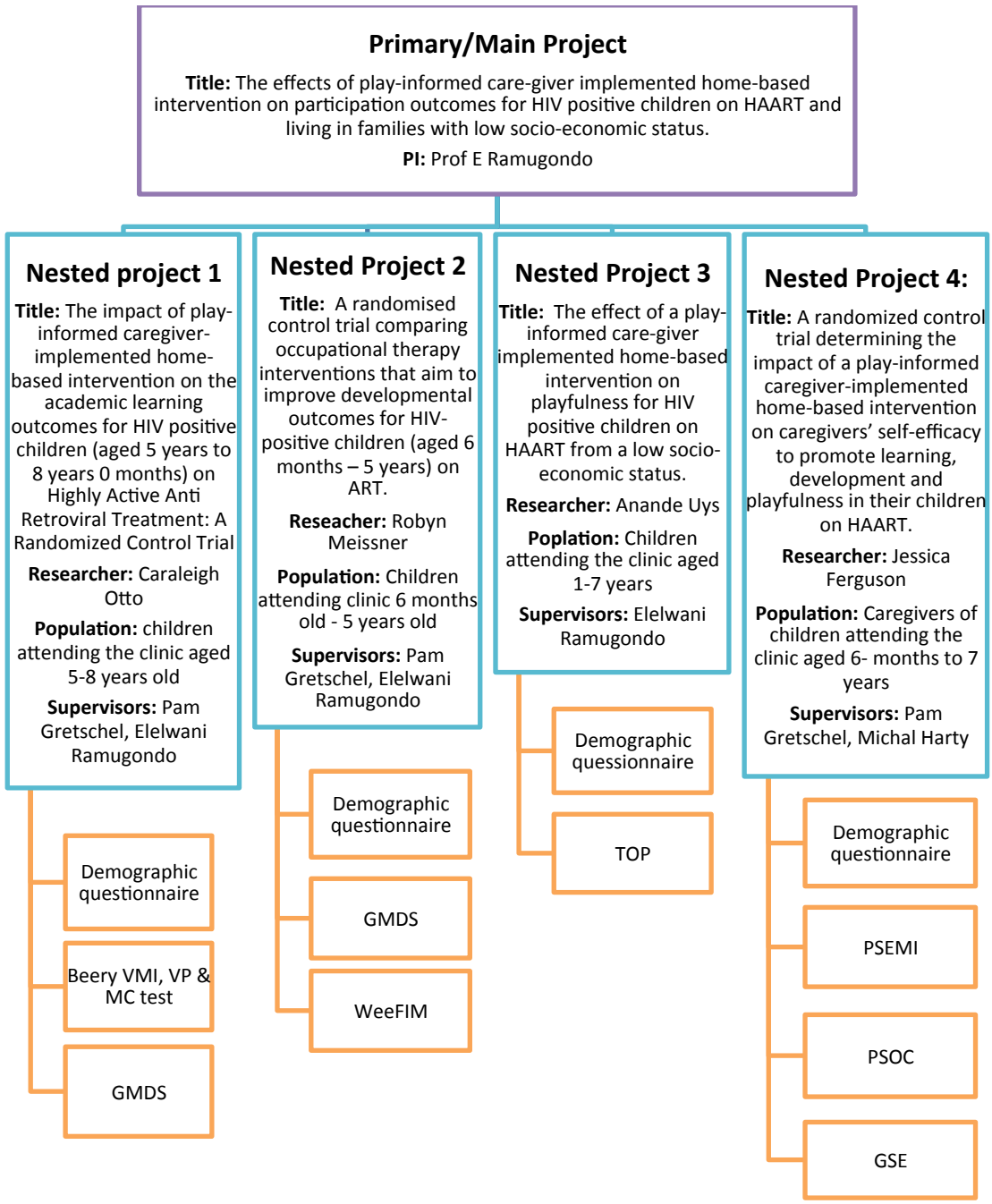
Appendices

Appendix A: Project map



Appendix B: Ethical approval letters

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492 • **Facsimile** [021] 406 6411
Email: Sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

23 October 2014

HREC/REF: 773/2014

Mrs P Gretschel
Occupational Therapy
Health & Rehab Sciences
F-45
OMB

Dear Mrs Gretschel

Project Title: IMPROVING DEVELOPMENTAL OUTCOMES FOR HIV-POSITIVE CHILDREN (AGED 6 MONTHS -5 YEARS) ON HAART THROUGH PLAY-INFORMED CAREGIVER-IMPLEMENTED HOME-BASED INTERVENTION (MSc-candidate- R Meissner)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above mentioned study.

Approval is granted for one year until the 30 October 2015.

Please submit a progress form, using the standardised Annual Report Form, if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

We acknowledge that the following student:-Robyn Meissner is also involved in this project.

Please note that the on-going ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Federal Wide Assurance Number: FWA00001637.

Hrec/ref:773/2014

UNIVERSITY OF CAPE TOWN

Faculty of Health Sciences
Human Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
e-mail: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/research/humanethics/forms

17 September 2013

HREC REF: 560/2013

A/Prof E Ramugondo
Occupational Therapy
Health & Rehab
F56.76, OMB

Dear A/Prof Ramugondo

PROJECT TITLE: THE EFFECTS OF PLAY-INFORMED CARE GIVER IMPLEMENTED HOME-BASED INTERVENTION ON PARTICIPATION OUTCOMES FOR HIV POSITIVE CHILDREN ON HAART AND LIVING IN FAMILIES WITH LOW SOCIO-ECONOMIC –STATUS

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th September 2014

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/research/humanethics/forms)

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC. REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN ETHICS
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

s.thomas

HUMAN RESEARCH ETHICS COMMITTEE
25 SEP 2014
HEALTH SCIENCES FACULTY UNIVERSITY OF CAPE TOWN

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30.9.2015
☐ Not approved	See attached comments		
Signature Chairperson of the HREC		Date Signed	26/9/14

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	25/09/2014		
HREC REF Number	HREC REF: 560/2013	Current Ethics Approval was granted until	30 September 2014
Protocol title	The effects of play-informed care-giver implemented home-based intervention on participation outcomes for HIV positive children on HAART and living in families with low socio-economic status		
Protocol number (if applicable)	N/A		
Are there any sub-studies linked to this study?		☐√ Yes ☐ No	
If yes, could you please provide the HREC Ref's for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.		PhD - HREC/REF 605/2012: This is not strictly a sub-study, but a parallel one, focussed on the design process of the intervention in the main study. It followed action research methodology within a case study approach. Masters Sub-Studies: Other than being true sub-studies, with a separate bigger study, these in fact make-up the bigger study, with the Masters students as co-researchers to the main study. This caused immense confusion for us early on, elaborated on further under Progress of Study. These Masters studies are under-going departmental research review, with 3 of 4 having just submitted rebuttal letters and revised proposals last week.	
Principal Investigator	A/Prof Elelwani Ramugondo		

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Appendix C: PICIHBI session outline and 'GOBox' items

Toddler Group (6months to 2 years)

Session	Skill Focus	Box items
1	Introduction and gross motor skills	Bean bag, bubbles, soft material ball, push toy, stubby wax crayons, book, knob puzzle, materials to make puppet, stacking cups, building blocks, toothbrush, flip file (for caregiver)
2	Play: preconstruction and discovery	
3	Fine motor skills	
4	Early literacy and language	
5	Self-care and independence	
6	Gross motor skills	
7	Play: preconstruction and discovery	
8	Fine motor skills	
9	Early literacy and language	
10	Self-care and conclusion	

Pre-school Group (3-5 years)

Session	Skill Focus	Box items
1	Introduction and gross motor skills	Bubbles, playdough, ring-o-links, threading lace, beads, crayons, book, scissors, glue, blank exercise books, beanbag, building blocks, ball, ribbon, puzzle, colouring-in book, flip file (for caregiver)
2	Fine motor skills	
3	Literacy and language	
4	Position, body awareness and visual perception	
5	Size and number	
6	Gross motor skills	
7	Fine motor skills	
8	Literacy and language	
9	Shape	
10	Size and number	

Foundation Phase Group (6-8 years)

Session	Skill Focus	Box items
1	Introduction and gross motor skills	Tennis ball, ribbon, disk counters, threading lace, pencil crayons, scissors, glue, sharpener, number grid, chalk, ruler, UNO cards, dice, addition/subtraction flash cards, white board marker, lines and curls, alphabet cards, blank exercise book, fishing rod, fish, paper clips, pencil crayons, pencils, eraser, alphabet chart (in appropriate languages), picture puzzle, 16pc puzzle, literacy bingo boards and cards, literacy dominoes, word prefixes and suffixes, book, home-made book, colouring-in book, ruler, plasticine, flip file (for caregiver)
2	Fine motor skills	
3	Speaking and listening, basic concepts (Literacy)	
4	Shapes (Numeracy)	
5	Patterns (Numeracy)	
6	Letters and phonics (Literacy)	
7	Counting (Numeracy)	
8	Letters and phonics (Literacy)	
9	Calculations (Numeracy)	
10	Reading and expression (Literacy)	

Appendix D: Demographic Questionnaire

Demographics Form

to be filled in by primary caregiver

Grey sections are to be filled in by researchers only

Administrated by: _____

Participant number/code: _____

Instructions: Please read the questions carefully and answer according to what applies to you and your family. Please ensure you answer all the questions. If you need any clarification on a question please ask the researcher or assistant to help you. Some questions require you to tick the relevant box related to your answer and other questions require you to write in your response. Please read the question to know whether you should tick only ONE option – if more than one option applies tick the one that applies the most. Some question will say that you can tick more than one option. If you make a mistake and mark the incorrect box, clearly scratch out the box and tick the new, correct answer. The questions are written in Xhosa in italics below the English question. If you need further assistance with language translation, please ask an assistant. Please answer honestly. Remember your results are kept confidential.

CAREGIVER'S DETAILS

1. How much time during the week are you usually with your child? This refers to time awake with the child therefore does not include sleeping time. Please tick only ONE answer.
Lingaphi ixesha olichithayo nomntwana wakho?
- ☐ Less than 7 hours per week
- ☐ 8 to 20 hours per week
- ☐ more than 20 hours per week (most of your time is spent with the child) 1. ____

2. What is your home language? Tick ONE answer.
Ulthetha oliphi ulwimi?
- ☐ English
- ☐ Afrikaans
- ☐ isiXhosa
- ☐ isiZulu
- ☐ Shona
- ☐ seSotho
- ☐ Other (specify) _____ 2. ____

3. Please indicate which ONE of the 3 following languages is MOST spoken in your home. Tick ONE answer.
Bonise lolphi ulwimi kula mathathu enilisebenzisa endlini.
- ☐ English
- ☐ Afrikaans
- ☐ isiXhosa 3. ____

4. What language do you prefer to read? Tick ONE answer.
Ufuna ufunda ngoluphi ulwimi.
- ☐ I cannot read
- ☐ English
- ☐ Afrikaans
- ☐ Xhosa
- ☐ I cannot read any of these specific languages 4. ____

Page | 1

5. What is YOUR (caregiver) age?
Mingaphi iminyaka yakho? _____ 5. ____

6. What is YOUR (caregiver) gender? (*Please tick your answer*)
Sithini isini sakho?
- ☐ Male
- ☐ Female 6. ____

7. What is YOUR (caregiver) highest level of education COMPLETED? Tick ONE answer.
Loluphi ubanga oluphezulu ufwenzileyo?
- ☐ None
- ☐ Grade 1
- ☐ Grade 2
- ☐ Grade 3
- ☐ Grade 4
- ☐ Grade 5
- ☐ Grade 6
- ☐ Grade 7
- ☐ Grade 8
- ☐ Grade 9
- ☐ Grade 10
- ☐ Grade 11
- ☐ Grade 12 (Matric)
- ☐ 1 year post school
- ☐ 2 years post school
- ☐ 3 years post school
- ☐ 4 or more years post school 7. ____

8. Are you the biological parent of the child?
Ungumzali womntwana?
- ☐ Yes
- ☐ No 8. ____

9. If you answered 'no' to the above question, what is your relationship with the child?
Ukuba awunguye uyintoni emntwaneni?
- ☐ Grandparent
- ☐ Aunt / uncle
- ☐ Sister / brother
- ☐ Foster parent
- ☐ Other. Please specify _____ 9. ____

10. How many children under the age of 18 do you take care of, in total (including child attending clinic)?
Bangaphi abantwana abanakekelwayo abangaphantsi kweminyaka elishumi elinesibhozo?
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7
- ☐ more than 7 10. ____

Page | 2

11. How old are the other children in the house? Fill in the children's ages in the gaps below.
Ungowesingaphi umntwana kubantwana bakho endini?

Age of child 1: _____; age of child 2: _____; age of child 3: _____; age of child 4 _____;
age of child 5: _____; age of child 6: _____; age of child 7: _____ 11. ____

12. How many other adults over the age of 18 do you live with at home?
Bangaphi abanye abantu abadala abangaphezulu kweminyaka elishumi elinesi bhoze?
- ☐ 0, I do not live with any other adults
- ☐ 1 other
- ☐ 2 others
- ☐ 3 others
- ☐ 4 others
- ☐ 5 others
- ☐ 6 others
- ☐ 7 others
- ☐ more than 7 others. Specify amount: ___ others. 12. ____

13. What is the total amount of money that you and your family (who you live with) live off every month? This INCLUDES salaries, grants and all other sources of income. Tick ONE answer.
Yimalini imali alubanayo usapho lwakho ngempela nyanga?
- ☐ No income
- ☐ R1 - R400
- ☐ R401 - R800
- ☐ R801 - R1 600
- ☐ R1 601 - R3 200
- ☐ R3 201 - R6 400
- ☐ R6 401 - R12 800
- ☐ R12 801 - R25 600
- ☐ R25 601 - R51 200
- ☐ R51 201 - R102 400
- ☐ R102 401 or more 13. ____

14. What is YOUR (caregiver) level of employment? Tick all that apply.
Lithini izinga lomsebenzi/lengzesha?
- ☐ Unemployed: ☐ Looking for work ☐ Stay at home mom/parent ☐ Retired
- ☐ Kidzpositive Beadwork project
- ☐ Self-employed
- ☐ Part-time employment
- ☐ Full-time employment
- ☐ Seasonal/occasional employment 14. ____

CHILD'S DETAILS

15. What is your child's date of birth?
Uzelwe nini umntwana wakho? _____ 15. ____

Page | 3

16. How many weeks were you/the biological mother pregnant when the child was born?
Ubuneveki ezingaphi ngoki ubunkhule lwe uzaku beleko?
- ☐ Under 29 weeks. The child was born very early – more than 3 months early (very premature).
- ☐ 29 to 36 weeks. The child was born early (premature)
- ☐ 37 weeks or more. The child was born at full term.
- ☐ I do not know 16. ____

17. Were there any problems during birth?
Zibekhona ingxaki xa ubeleka?
- ☐ Yes. Please specify _____
- ☐ No
- ☐ I do not know 17. ____

18. Are there any other confirmed medical diagnoses (other than HIV+)?
Zibekhona ezingxelo ezibonwe kuwe ngaggirha ngaphandle ko gowulayo?
- ☐ Yes. Please specify _____
- ☐ No
- ☐ I do not know 18. ____

19. Where is your child USUALLYduring the day in the week? Tick ONE answer.
Ubaphi umntwana wakho emini phakathi, evekini?
- ☐ My child attends crèche/play school
- ☐ My child attends formal school
- ☐ My child stays with me during the day
- ☐ My child goes to another friend/family member/day mother during the day 19. ____

20. What is the name of your child's school?
Ngubaniganma lomntwana wakho esikoleni?

Please specify _____
- ☐ My child does not go to school. 20. ____

21. If your child is in school, what grade is he/she in?
Ukuba umntwana wakho useskolweni/wenza eliphi ibanga?
- ☐ Crèche
- ☐ Grade R
- ☐ Grade 1
- ☐ Grade 2
- ☐ Grade 3
- ☐ My child is not in school 21. ____

22. If your child is in school, is it a mainstream (normal) school or special school?
Ingaba umntwana wakho usesikolweni? Sisikolo somntu wonke okanye sesemeko emalunga nomntwana?
- ☐ Mainstream (normal) school
- ☐ Special school
- ☐ My child is not in school 22. ____

23. If your child is in school, has he or she failed any grades?
Mntwana wakho ukhe waliphinda ibanga?
- ☐ Yes. Specify grade _____
- ☐ No
- ☐ My child is not in school 23. ____

Page | 4

24. If your child is attending school, what is the MAIN language medium of the school that is taught to your child? Tick ONE answer.
Ukube umntwana wakho uyafunda luluphi iiwini lakhe lokuqala?

- ☐ English
- ☐ Afrikaans
- ☐ Xhosa
- ☐ Other. Please specify _____
- ☐ My child is not in school

24. ____

25. How long has your child been on HAART?
Unexesha elingakanani umntwana wakho efumana unyango?

- ☐ Less than 2 months
- ☐ 2 - 6 months
- ☐ 7 - 11 months
- ☐ 1 year
- ☐ 2 years
- ☐ 3 years
- ☐ 4 years
- ☐ 5 years
- ☐ 6 years
- ☐ 7 years
- ☐ 8 years

25. ____

26. How do you feel about your child's learning, development and play skills? Tick ONE answer.
Uva njani ngezifundo zomntwana wakho, kwizakhono zophuhliso?

- ☐ I am very concerned that he/she is developing very slowly and is far behind other children of the same age
- ☐ I feel that he/she is developing a little slower than other children of the same age
- ☐ I feel he/she is developing the same as other children his/her age
- ☐ I feel that he/she is developing a little better than other children of the same age
- ☐ I feel that he/she is developing very well and is far above the average compared to other children of the same age

26. ____

27. Is your child currently attending any of the following services? Tick ALL that apply
Ingaba umntwana wakho uyazifunda ezizifundo zilandelayo?

- ☐ Speech therapy
- ☐ Physiotherapy
- ☐ Occupational therapy (OUTSIDE OF GSH G26 clinic)
- ☐ Remedial teaching
- ☐ Psychologist
- ☐ Audiology
- ☐ Dietician
- ☐ Other. Please specify _____
- ☐ None, my child is not attending any other support services outside of GSH

27. ____

28. Has your child previously attended any of the following services? Tick ALL that apply
Ingaba umntwana wakho ukhe wahlangana nenye yesinkqubo?

- ☐ Speech therapy
- ☐ Physiotherapy
- ☐ Occupational therapy (OUTSIDE OF GSH G26 clinic)
- ☐ Remedial teaching
- ☐ Psychologist
- ☐ Audiology
- ☐ Dietician
- ☐ Other. Please specify _____
- ☐ None, my child is not attending any other support services outside of GSH

28. ____

29. Has your child ever had their hearing tested? (at school or at hospital/clinic)?
Umntwana wakho ukhe waxilongelwa ndlebe esikolweni okanye esibhedlele/eklinikini?

- ☐ Yes: result: ☐ normal/good hearing; ☐ poor hearing
- ☐ No
- ☐ I do not know

29. ____

30. Has your child ever had their vision tested? (at school or at hospital/clinic)?
Umntwana wakho uke waxila ngelwa amehlo? Esikolweni okanye esibhedlele/eklinikini?

- ☐ Yes: result: ☐ normal/good vision; ☐ poor vision
- ☐ No
- ☐ I do not know

30. ____

31. Can you specify any concerns that you might have about your child's development (if any).
Ungasichazela ngendlela ovangayo ngokukhula komntwana wakho.

_____
_____
_____

31. ____

32. Who is the MAIN person who plays with the child? Tick ONE answer.
Ngubani oyena mntu udlala nomntwana?

- ☐ The child mainly plays by himself/herself
- ☐ You, the caregiver
- ☐ Another adult (over 18 years)
- ☐ A younger child in your house
- ☐ An older child in your house (that is younger than 18 years)
- ☐ Another child outside the house eg (neighbour or friend)

32. ____

33. What are 3 of your child's favourite toys/things that s/he plays frequently with?
Zintoni ezintathu zokudlala ezinthandwa ngumntwana wakho?

1. _____
2. _____
3. _____

33. ____

34. Do you have a television inside your home?
Unaye umabona-kude?

- ☐ Yes
- ☐ No, we do not own a television.

34. ____

35. Is the television on every day?
Umabona-kude udlala yonke imihla?

- ☐ Yes
- ☐ No
- ☐ We do not own a television.

35. ____

36. Does your child watch television every day?
Umntwana wakho ubukele yonke imihla umabonakude?

- ☐ Yes
- ☐ No
- ☐ We do not own a television.

36. ____

37. How many hours a day does your child usually watch television? Tick ONE answer.
Uxubukela iyure ezingaphi umntwana wakho umabonakude ngosuku?

- ☐ Less than 1 hour
- ☐ 1 hour
- ☐ 2 hours
- ☐ 3 hours
- ☐ 4 hours
- ☐ 5 hours or more
- ☐ We do not own a television.

37. ____

38. Does your child play in the same room/area as the television? Tick ONE answer.
Ingaba umntwana wakho udlala kwegumbi linye linomabonakude okanye kwelinye?

- ☐ Yes
- ☐ No
- ☐ No, my child is not allowed to play inside.
- ☐ We do not own a television

38. ____

39. Where inside the house does your child play (if they are allowed to play inside)?
Udlala phi imntwana wakho endlwini?

_____
_____
_____

39. ____

——————— Thank you for taking the time to complete this form ———————

THIS PAGE IS TO BE FILLED IN BY RESEARCHER
Separate page of info to get from file or Road to Health card

Participant Code: _____

a) Primary G26 clinic Dr: ☐ Dr Mandy Ingles ☐ Dr Gwen Norton; ☐ Dr Rebecca Sher/Melissa Pascoe; ☐ Dr Kathie Walker; ☐ Dr Dale Zief *(Dr Wright is no longer with us so cannot be an answer)* a. ____
b) Primary Counsellor: ☐ Bonnie; ☐ Nowolo; ☐ Pumla; ☐ Sabrina; ☐ Vivienne b. ____

Birth History

c) Gestation _____ c. ____
d) Birth weight: _____ d. ____
e) Apgar 1min: 5min: ☐ not recorded _____ e. ____
f) Birth delivery: ☐ NVD; ☐ C/S; ☐ Unknown f. ____
g) Birth complications ☐ No problems; ☐ Problems. Specify:

_____
_____ g. ____

Medical History

h) Date Started HAART _____ h. ____
i) Date Enrolled at G26 clinic _____ i. ____
j) Defaults History _____ j. ____
k) Line of Treatment ☐ 1st line; ☐ 2nd line; ☐ 3rd line k. ____
l) TB History ☐ No History; ☐ Yes History: dates _____ l. ____
m) Other Diagnoses ☐ No ☐ Yes: specify: _____ m. ____

Complimentary services

n) Other services attended in past. Eg dietician (Specify when, how often, GSH or service site etc)
Services currently attending (Specify when, how often, GSH or service site etc)

_____
_____
_____
_____
_____ n. ____

Appendix E: Institution approval letters

WC DoH Letter for Permission to Conduct Pilot Study at Victoria Hospital

School of Health and Rehabilitation Sciences

Faculty of Health Sciences

Divisions of Communications Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

F45 Old Main Building, Groote Schuur Hospital,

Observatory 7925

Western Cape Department of Health

To Whom It May Concern:

This is a formal request for permission to conduct a pilot study on a population comprised of HIV positive caregiver-child dyads who attend a paediatric out-patients clinic at Victoria Hospital.

The proposed study aims to investigate effects of play-informed care-giver implemented home-based intervention (PI-CIHBI) on development for HIV positive children (Aged 6 months to 5 years old) on Highly Active Anti-retroviral Treatment (HAART) and living in families with low socio-economic status. There are well-established negative long-term consequences for development for children affected with Acquired Immune Deficiency Syndrome (AIDS). While HAART has proven to be effective in prolonging life expectancy in children living with HIV/AIDS, access to comprehensive health care is critical for these children to continue enjoying quality of life. Caregivers of HIV+ children in South Africa often face contextual challenges that often limit their ability to support their children's optimal participation in learning, development and play. Consequently, the potential of these children to meet their participation needs as adolescents and adults is compromised.

There are limited studies detailing what may be appropriate and possibly effective responses to developmental, functional and participatory challenges for children infected with HIV, especially those on ART or HAART. Given that home-based intervention has been proven to be effective in improving cognitive and motor development for HIV positive children from families with low SES, and may consequently impact functional and participation outcomes for such children, this kind of intervention may relieve the cost burden on the South African state for rehabilitation services.

Possible positive impact on development for HIV infected children through PI-CIHBI may hold important promise for early childhood development in the country. A description of appropriate PI-CIHBI for families with low SES will inform relevant occupational therapy in South Africa. Efficacy in promoting children's meaningful and productive participation in life will be affirming for both caregivers and therapists.

As part of the research, the Griffiths Mental Development Scales – Revised & Extended Revised (GMDS-R & ER) will be used to collect data at baseline, and twice at six monthly intervals. A pilot study is necessary to establish inter-rater reliability between two co-researchers on the GMDS-R & ER. 7 (10% of the main study sample) children will be recruited from the out-patient clinic at Victoria Hospital. These children are currently seen by one of the occupational therapists for individual occupational therapy services. Data obtained from the assessment will inform ongoing intervention.

The study will adhere strictly to ethical principles as outlined in the Declaration of Helsinki (World Medical Association 2013). Ethics approval has been obtained from the Faculty of Health Sciences Human Research Ethics Committee of the University of Cape Town (HREC Reference number 560/2013).

Caregiver informed consent will be sought before participation in the study resumes. There will be no coercion of any form in order to gain participation from the study population and each caregiver-child dyad may withdraw from the study at any point in time, free of prejudice should they so wish. No personal information will be collected as data during the study. The relevant hospital management personnel will be approached to seek consent to conduct this study following a positive response from the Department of Health.

Please forward any question or concern you may have regarding this research to contact details furnished below.

Researcher:

Robyn Meissner (robyn.jess@gmail.com; 0824801247)

Principal Investigator:

A/Prof Professor Elelwani Ramugondo

Elelwani.Ramugondo@uct.ac.za

021- 406 6048

Chairperson of the UCT faculty of Health Sciences Human Research Ethics Committee:

Professor Marc Blockman

021- 406 6496

Letter to Clinical Manager for Permission to Conduct Pilot Study at Victoria Hospital

School of Health and Rehabilitation Sciences

Faculty of Health Sciences

Divisions of Communications Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

F45 Old Main Building, Groote Schuur Hospital,

Observatory 7925

Tel: +27 (0) 21 406 6401 Fax: +27 (0) 21 406 6323

Clinic Manager

Victoria Hospital

To Whom It May Concern:

This is a formal request for permission to conduct a pilot study on a population comprised of HIV positive caregiver-child dyads who attend a paediatric out-patients clinic at Victoria Hospital.

The proposed study aims to investigate effects of play-informed care-giver implemented home-based intervention (PI-CIHBI) on development for HIV positive children (Aged 6 months to 5 years old) on Highly Active Anti-retroviral Treatment (HAART) and living in families with low socio-economic status. There are well-established negative long-term consequences for development for children affected with Acquired Immune Deficiency Syndrome (AIDS). While HAART has proven to be effective in prolonging life expectancy in children living with HIV/AIDS, access to comprehensive health care is critical for these children to continue enjoying quality of life. Caregivers of HIV+ children in South Africa often face contextual challenges that often limit their ability to support their children's optimal participation in learning, development and play. Consequently, the potential of these children to meet their participation needs as adolescents and adults is compromised.

There are limited studies detailing what may be appropriate and possibly effective responses to developmental, functional and participatory challenges for children infected with HIV, especially those on ART or HAART. Given that home-based intervention has been proven to be effective in improving cognitive and motor development for HIV positive children from families with low SES, and may consequently impact functional and participation outcomes for such children, this kind of intervention may relieve the cost burden on the South African state for rehabilitation services.

Possible positive impact on development for HIV infected children through PI-CIHBI may hold important promise for early childhood development in the country. A description of appropriate PI-CIHBI for families with low SES will inform relevant occupational therapy in South Africa. Efficacy in promoting children's meaningful and productive participation in life will be affirming for both caregivers and therapists.

As part of the research, the Griffiths Mental Development Scales – Revised & Extended Revised (GMDS-R & ER) will be used to collect data at baseline, and twice at six monthly intervals. A pilot study is necessary to establish inter-rater reliability between two co-researchers on the GMDS-R & ER. 7 (10% of the main study sample) children will be recruited from the out-patient clinic at Victoria Hospital. These children are currently seen by one of the occupational therapists for individual occupational therapy services. Data obtained from the assessment will inform ongoing intervention.

The study will adhere strictly to ethical principles as outlined in the Declaration of Helsinki (World Medical Association 2013). Ethics approval has been obtained from the Faculty of Health Sciences Human Research Ethics Committee of the University of Cape Town (HREC Reference number 560/2013).

Caregiver informed consent will be sought before participation in the study resumes. There will be no coercion of any form in order to gain participation from the study population and each caregiver-child dyad may withdraw from the study at any point in time, free of prejudice should they so wish. No personal information will be collected as data during the study. The relevant hospital management personnel will be approached to seek consent to conduct this study following a positive response from the Department of Health.

Please forward any question or concern you may have regarding this research to contact details furnished below.

Researcher:

Robyn Meissner (robyn.jess@gmail.com; 0824801247)

Principal Investigator:

A/Prof Professor Elelwani Ramugondo

Elelwani.Ramugondo@uct.ac.za

021- 406 6048

Chairperson of the UCT faculty of Health Sciences Human Research Ethics Committee:

Professor Marc Blockman

021- 406 6496

WC DoH Letter for Permission to Conduct Research at Groote Schuur Hospital

School of Health and Rehabilitation Sciences

Faculty of Health Sciences

Divisions of Communications Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

F45 Old Main Building, Groote Schuur Hospital,

Observatory 7925

Western Cape Department of Health

To Whom It May Concern:

This is a formal request for permission to conduct a research study on a population comprised of HIV positive caregiver-child dyads who attend a paediatric out-patients clinic at Groote Schuur Hospital.

The proposed study aims to investigate effects of play-informed care-giver implemented home-based intervention (PI-CIHBI) on developmental outcomes for HIV positive children (Aged 6 months to 5 years old) on Highly Active Anti-retroviral Treatment (HAART) and living in families with low socio-economic status. PI-CIHBI will be compared with standard one-on-one occupational therapy intervention to see if it will produce equivalent or even greater improvement in child development. There are well-established negative long-term consequences for learning and development for children affected with Acquired Immune Deficiency Syndrome (AIDS). While HAART has proven to be effective in prolonging life expectancy in children living with HIV/AIDS, access to comprehensive health care is critical for these children to continue enjoying quality of life. Caregivers of HIV+ children in South Africa often face contextual challenges that often limit their ability to support their children's optimal development. Consequently, the potential of these children to meet their participation needs as adolescents and adults is compromised.

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Possible positive impact on development and self-care for HIV infected children through PI-CIHBI may hold important promise for early childhood development in the country. A description of appropriate PI-CIHBI for families with low SES will inform relevant occupational therapy in South Africa. Efficacy in promoting children's meaningful and productive participation in life will be affirming for both caregivers and therapists.

The study will involve 70 caregiver-child dyads over a year. Data will be collected using the Griffiths Mental Development Scales – Revised & Extended Revised (GMDS – R & ER) and

the Wee Functional Independence Measure on children aged 6 months to 5 years old at base-line and twice at six monthly intervals. Intervention in both the experimental and control group will occur monthly, following the same scheduling currently followed for clinic visits.

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Letter to Clinic Manager for Permission to Conduct Research at Groote Schuur Hospital

School of Health and Rehabilitation Sciences

Faculty of Health Sciences

Divisions of Communications Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

F45 Old Main Building, Groote Schuur Hospital,

Observatory 7925

Clinic Manager

Groote Schuur Hospital

To whom it may concern.

This is a formal request for permission to conduct a research study on a population comprised of HIV positive caregiver-child dyads who attend a paediatric out-patients clinic at Groote Schuur Hospital.

The proposed study aims to investigate effects of play-informed care-giver implemented home-based intervention (PI-CIHBI) on developmental outcomes for HIV positive children (Aged 6 months to 5 years old) on Highly Active Anti-retroviral Treatment (HAART) and living in families with low socio-economic status. PI-CIHBI will be compared with standard one-on-one occupational therapy intervention to see if it will produce equivalent or even greater improvement in child development. There are well-established negative long-term consequences for learning and development for children affected with Acquired Immune Deficiency Syndrome (AIDS). While HAART has proven to be effective in prolonging life expectancy in children living with HIV/AIDS, access to comprehensive health care is critical for these children to continue enjoying quality of life. Caregivers of HIV+ children in South Africa often face contextual challenges that often limit their ability to support their children's optimal development. Consequently, the potential of these children to meet their participation needs as adolescents and adults is compromised.

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021- 406 6496

Western Cape Government
Health

GROOTE SCHUUR HOSPITAL

Enquiries: Dr Bhavna Patel
E-mail : *Bhavna.Patel@westerncape.gov.za*

Associate Professor E. Ramugondo
Occupational Therapy
Health & Rehabilitation
F56.76 – Old Main Building

E-mail: elelwani.ramugondo@uct.ac.za / paul.roux@uct.ac.za

Dear A/Professor Ramugondo

RESEARCH PROJECT: The Effects of Play-informed Care Giver Implemented Home-Based Intervention on Participation Outcomes for HIV Positive Children on Haart and Living in Families with Low Socio-Economic Status

Your recent letter to the hospital refers.

You are hereby granted permission to proceed with your research.

Please note the following:

a) Your research may not interfere with normal patient care
b) Hospital staff may not be asked to assist with the research.
c) No hospital consumables and stationary may be used.
d) **No patient folders may be removed from the premises or be inaccessible.**
e) Please introduce yourself to the person in charge of an area before commencing.
f) Please provide the research assistant/field worker with a copy of this letter as verification of approval.
g) Confidentiality must be maintained at all times.

I would like to wish you every success with the project.

Yours sincerely

DR BHAVNA PATEL
CHIEF EXECUTIVE OFFICER
Date: 14th January 2014

C.C. Mr Lionel Naidoo
Dr Janine Hendricks
Mrs Rogini Pillay

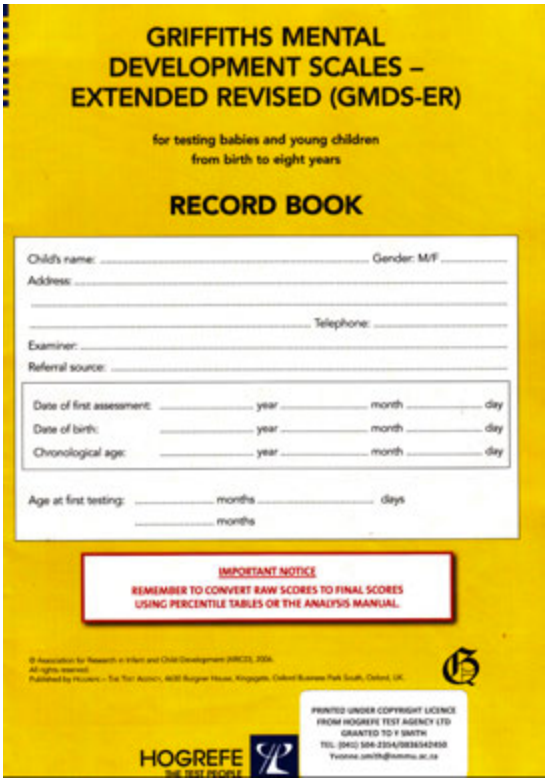
G46 Management Suite, Old Main Building,
Observatory 7925

Tel: +27 21 404 6288 fax: +27 21 404 6125

Private Bag X,
Observatory, 7935

www.capegateway.go.v.za

Appendix F: GMDS record book



GRIFFITHS MENTAL DEVELOPMENT SCALES – EXTENDED REVISED (GMDS-ER)

for testing babies and young children from birth to eight years

RECORD BOOK

Child's name: ..... Gender: M/F .....

Address: .....

..... Telephone: .....

Examiner: .....

Referral source: .....

Date of first assessment: ..... year ..... month ..... day

Date of birth: ..... year ..... month ..... day

Chronological age: ..... year ..... month ..... day

Age at first testing: ..... months ..... days

..... months

IMPORTANT NOTICE

REMEMBER TO CONVERT RAW SCORES TO FINAL SCORES USING PERCENTILE TABLES OR THE ANALYSIS MANUAL.

HOGREFE THE TEST PEOPLE

Child's name: ..... Date of birth: .....

Gestation: ..... Birth weight: ..... Delivery: .....

Position in family: ..... Age of siblings: .....

Mother's name: ..... Father's name: .....

Age: ..... Nationality: ..... Age: ..... Nationality: .....

Occupation: ..... Occupation: .....

Relevant history: .....

Reason for referral: .....

Vision: ..... Hearing: .....

Summary of test results

Subscales	A	B	C	D	E	F
Section I (months)*						
Section II (months)*						
Section III (items x 2)*						
Section IV (items x 2)*						
TOTAL RAW SCORE for subscales						
Percentile score						
Confidence range						
z-score						
Age equivalent score (months)						
Date of test						
Chronological age						
Corrected age						

GQ*

*Use MA in months for Sections I and II; items x 2 for Sections III and IV.
*Add 'months' of MA for Sections I and II to 'items x 2' for Sections III and IV.
*Obtain the GQ raw score by taking the **average** of the **raw scores** for the six subscales.

Clinical observations/behaviour/diagnosis: .....

3

SECTION I:

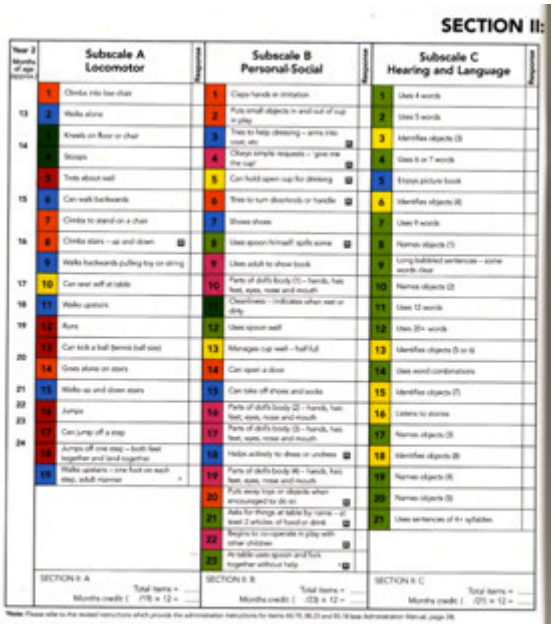
Year 1 Months of age (approx.)		Subscale A Locomotor	Response		Subscale B Personal-Social	Response		Subscale C Hearing and Language	Response
1	1	Lifts chin when prone		1	Regards person – fleeting glance		1	Startled by sound	
	2	Pushes with feet against examiner's hands		2	Quieted when picked up		2	Listens to bell	
	3	Holds head erect for few seconds		3	Enjoys bath		3	Vocalisation other than crying	
	4	Kicks vigorously		4	Visually recognises mother		4	Cooing – one syllable	
	5	Lifts head up when prone		5	Follows moving persons with eyes		5	Makes two different sounds	
	6	Active in bath – kicks		6	Smiles		6	Listens to music	
	7	Rolls from side to back		7	Vocalises when talked to		7	Searches for sound with eyes	
2	8	Back firm when held in sitting position		8	Returns examiner's glance with smiling or cooing		8	Searches for sound with head movements	
	9	Lifts head when in dorsal position		9	Friendly to strangers		9	Laughs aloud	
3	10	Lifts head, shoulders and chest when prone		10	Expresses 2 or more recognisable emotions, e.g. pleasure, fear, sadness, distress or anger		10	Talks (babbles) to persons	
	11	Holds head erect continuously		11	Stops crying when talked to		11	Cries or stops crying on hearing music	
	12	Lifts head and shoulders, dorsal		12	Frolics when played with		12	Turns head deliberately to bell	
4	13	Crawling reaction 1: draws up knees, etc.		13	Regards mirror image 1: looks at		13	Makes 4 different sounds	
	14	Rolls from side to side via dorsal position		14	Reacts adult who tries playfully to take ring		14	Listens to turning fork	
	15	Sits with slight support		15	Turns head in person talking or singing		15	Responds when called	
	16	Plays with own toes		16	Holds a spoon		16	Manipulates bell	
5	17	Stepping reaction 1: dancing movements		17	Anticipatory movements when about to be lifted		17	Shouts for attention	
	18	Sits alone for a short time		18	Knows strangers from familiar friends		18	2-syllable babble	
6	19	Crawling reaction 2: can turn around when left on floor (pivoting)		19	Prompt reaction to situation, e.g. at table, waiting to be fed		19	Listens to conversations	
	20	Crawling reaction 3: rises vigorously to crawl		20	Manipulates cup or spoon in play		20	Rings bell	
	21	Can roll from stomach to back (or from back to stomach)		21	Displeased if toy is taken		21	Looks at pictures for a few seconds	
7	22	Crawling reaction 4: makes some progress forwards or backwards		22	Holds and bites biscuits, rusks, ice-cream wafers, etc.		22	Singing tones	
	23	Stepping reaction 2: one foot in front of the other		23	Interested in small children (other than own siblings)		23	One word (mama, dada, etc.) definite and meaningful	
8	24	Can be left sitting on floor		24	Helps to hold cup or mug for drinking		24	Babbled phrase: 4+ syllables	
	25	'Stands' when held up		25	Pulls off hat		25	Likes rhymes and jingles	
	26	Sits well in a chair		26	Drinks from any open cup or mug if held to, lips		26	Knows own name	
9	27	Crawling reaction 5: creeps on hands and knees, etc.		27	Stretches to be taken up		27	Babbled monologue when alone	
	28	Pulls self up by furniture		28	Finger feeds (thumb and forefinger), e.g. sultanas, 'smarties', etc.		28	Shakes head for 'No'	
	29	Can stand holding on to furniture		29	Picks up and drinks from lidded and closed feeder cup unaided		29	Uses 2 definite words	
10	30	Side-steps round inside of cot or playpen holding rails		30	Responds socially to mirror image 2: smiles at or plays with		30	Reacts to music vocally	
	31	Climbs on a low hedge or step		31	Gives affection		31	Short babbled sentences	
11	32	Can walk when led		32	Plays very simple interactive games with others		32	Uses 3 words	
	33	Climbs stairs (up)		33	Plays with cup, spoon and saucer		33	Identifies objects (1)	
	34	Likes pushing pram, toy horse, etc.		34	Waves bye-bye		34	Tries definitely to sing	
12		Stands alone		35	Shows an interest in the activities of others		35	Identifies objects (2)	
		SECTION I: A	Total items = ... Months credit (..... /30) x 12 = ...		SECTION I: B	Total items = ... Months credit (..... /35) x 12 = ...		SECTION I: C	Total items = ... Months credit (..... /35) x 12 = ...

4

FIRST YEAR

	Subscale D Eye and Hand Co-ordination	Response		Subscale E Performance	Response	Notes and Comments
1	Follows moving light with eyes		1	Reflex grasp of examiner's finger		
2	Looks at bell-ring or toy momentarily		2	Reacts to paper 1: generalised physical movements		
3	Looks steadily at bell-ring held still		3	Energetic arm movements		
4	Follows moving bell-ring horizontally		4	Hand goes to mouth		
5	Follows moving bell-ring vertically		5	Holds rod		
6	Glances from one object to another		6	Plays with own fingers		
7	Follows moving bell-ring in a circle		7	Reacts to paper 2: vigorous head-turning		
8	Watches objects pulled along by string		8	Resists withdrawal of rod		
9	Grasps ring when given		9	Looks at yellow box on table		
10	Visually explores new environment		10	Grasps cube put in hand and holds it		
11	Reaches for ring and grasps		11	Shows interest in box		
12	Carries ring to mouth		12	Drops first cube for second		
13	Clutches at dangling ring		13	Reacts to paper 3: pulls it away		
14	Secures dangling ring		14	Takes cube or toy from table		
15	Hands explore table surface		15	Holds 2 cubes		
16	Plays with ring – shaking, banging, etc.		16	Manipulates cube or toy		
17	Reaches for and picks up string		17	Grasps box		
18	Looks for fallen object		18	Passes toy or cube from hand to hand		
19	Strikes one object with another		19	Reacts to paper 4: reaches for and takes		
20	Secures ring by means of string		20	Manipulates 2 objects at once		
21	Watches examiner scribble		21	Reacts to paper 5: plays with – tears, crumples		
22	Forefinger and thumb partly specialised		22	Lifts cup inverted over toy		
23	Dangles ring by string		23	Drops one cube for third		
24	Pre-prehension		24	Rattles box		
	Interested in motor car		25	Lifts lid off box		
	Likes holding little toys		26	Finds toy under cup		
27	Throws objects (record how child throws)		27	Tries to take cubes out of box		
28	Thumb opposition complete		28	Holds third cube		
29	Can hold pencil as if to mark on paper		29	Clicks 2 bricks together (= imitation)		
30	Can point with index finger		30	Manipulates box, lid and both cubes		
31	Plays pulling ring or toy by string		31	Removes both cubes from box		
32	Uses pencil on paper a little		32	Unwraps and finds toy or cube		
33	Preference for one hand			One-circle board		
	Plays pushing little cars along		34	Removes lids and both bricks from the other 2 boxes		
35	Can hold 4 cubes in hands at once		35	Puts 2 bricks back into any one box when encouraged to do so		
	SECTION I: D	Total items = ... Months credit (..... /30) x 12 = ...		SECTION I: E	Total items = ... Months credit (..... /35) x 12 = ...	

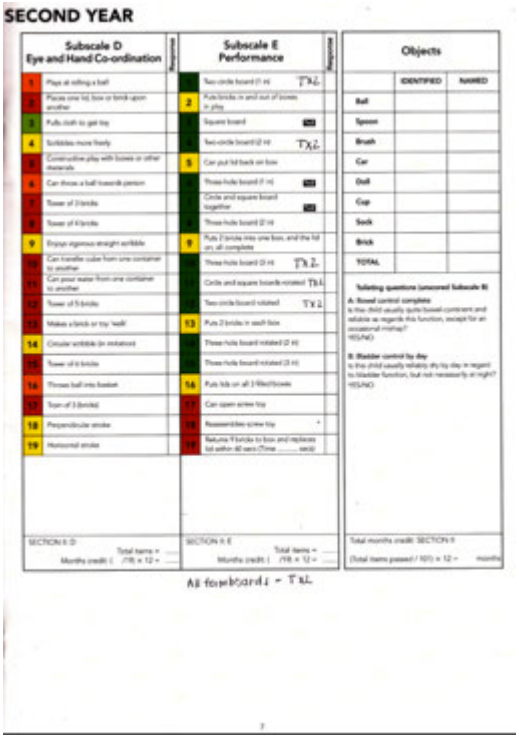
5



SECTION II:

Year 2 Months of age approx.	Subscale A Locomotor	Response	Subscale B Personal-Social	Response	Subscale C Hearing and Language	Response
13	1 Climbs into low chair		1 Claps hands or imitation		1 Uses 4 words	
	2 Walks alone		2 Puts small objects in and out of cup in play		2 Uses 5 words	
14	3 Kneels on floor or chair		3 Tries to help dressing – arms into coat, etc		3 Identifies objects (3)	
	4 Stoops		4 Obeys simple requests – 'give me the cup'		4 Uses 6 or 7 words	
	5 Trots about well		5 Can hold open cup for drinking		5 Enjoys picture book	
15	6 Can walk backwards		6 Tries to turn doorknob or handle		6 Identifies objects (4)	
	7 Climbs to stand on a chair		7 Shows shoes		7 Uses 9 words	
16	8 Climbs stairs – up and down		8 Uses spoon himself: spills some		8 Names objects (5)	
	9 Walks backwards pulling toy on string		9 Likes adult to show book		9 Long babbled sentences – some words clear	
17	10 Can wear self at table		10 Parts of doll's body (1) – hands, hair, feet, eyes, nose and mouth		10 Names objects (2)	
18	11 Walks upstairs		Cleanliness – indicates when wet or dirty		11 Uses 12 words	
19	12 Runs		12 Uses spoon well		12 Uses 20+ words	
	13 Can kick a ball (temis ball size)		13 Manages cup well – half full		13 Identifies objects (5 or 6)	
20	14 Goes alone on stairs		14 Can open a door		14 Uses word combinations	
21	15 Walks up and down stairs		15 Can take off shoes and socks		15 Identifies objects (7)	
22	16 Jumps		16 Parts of doll's body (2) – hands, hair, feet, eyes, nose and mouth		16 Listens to stories	
23	17 Can jump off a step		17 Parts of doll's body (3) – hands, hair, feet, eyes, nose and mouth		17 Names objects (9)	
24	18 Jumps off one step – both feet together and land together		18 Helps actively to dress or undress		18 Identifies objects (8)	
	19 Walks upstairs – one foot on each step, adult manner		19 Parts of doll's body (4) – hands, hair, feet, eyes, nose and mouth		19 Names objects (6)	
			20 Puts away toys or objects when encouraged to do so		20 Names objects (5)	
			21 Asks for things at table by name – at least 2 articles of food or drink		21 Uses sentences of 4+ syllables	
			22 Begins to co-operate in play with other children			
			23 At table uses spoon and fork together without help			
	SECTION II: A Total items = ___ Months credit (/19) x 12 = ___		SECTION II: B Total items = ___ Months credit (/23) x 12 = ___		SECTION II: C Total items = ___ Months credit (/21) x 12 = ___	

Note: Please refer to the revised instructions which provide the administration instructions for items 10,19, 20,23 and 23,18 (see Administration Manual, page 24).



SECOND YEAR

Subscale D Eye and Hand Co-ordination	Response	Subscale E Performance	Response
1 Plays at rolling a ball		1 Two-circle board (1 m) TAL	
2 Places one lid, box or brick upon another		2 Puts bricks in and out of boxes in play	
3 Pulls cloth to get toy		3 Square board	
4 Scribbles more freely		4 Two-circle board (2 m) TAL	
5 Constructive play with boxes or other materials		5 Can put lid back on box	
6 Can throw a ball towards person		Three-hole board (1 m)	
7 Tower of 3 bricks		Circle and square board together	
8 Tower of 4 bricks		Three-hole board (2 m)	
9 Enjoys vigorous straight scribble		9 Puts 2 bricks into one box, and the lid on: all complete	
10 Can transfer cube from one container to another		Three-hole board (3 m) TAL	
11 Can pour water from one container to another		Circle and square boards rotated TAL	
12 Tower of 5 bricks		Two-circle board rotated TAL	
13 Makes a brick or toy 'walk'		13 Puts 3 bricks in each box	
14 Circular scribble (in imitation)		Three-hole board rotated (2 m)	
15 Tower of 6 bricks		Three-hole board rotated (3 m)	
16 Throws ball into basket		16 Puts lids on all 3 Wed boxes	
17 Train of 3 (bricks)		17 Can open screw toy	
18 Perpendicular stroke		18 Reassembles screw toy	
19 Horizontal stroke		19 Returns 9 bricks to box and replaces lid within 40 secs (Time ..... secs)	
SECTION II: D Total items = ___ Months credit (/19) x 12 = ___		SECTION II: E Total items = ___ Months credit (/19) x 12 = ___	

All four boards - TAL

Objects	IDENTIFIED	NAMED
Ball		
Spoon		
Brush		
Car		
Doll		
Cup		
Sock		
Brick		
TOTAL		

Toileting questions (uncored Subscale II)

A: Bowel control complete
Is this child usually quite bowel continent and reliable as regards this function, except for an occasional mishap?
YES/NO

B: Bladder control by day
Is this child usually reliably dry by day in regard to bladder function, but not necessarily at night?
YES/NO

Total months credit: SECTION II
(Total items passed / 101) x 12 = ___ months

SECTION III: THIRD

Subscale A Locomotor	Response	Subscale B Personal-Social	Response	Subscale C Language	Response
1 Jumps off 1 step		1 Puts away toys when encouraged to do so		1 Names 10 objects in box	
2 Static balance 1: can stand on one foot for 5+ seconds		2 Gives first name		2 Picture vocabulary (12) INB: Administer after item FIX.10	
3 Can rise from kneeling without using hands		3 Assists with small household tasks on request		3 Defines by use (5+)	
4 Can run fast indoors or in a small outside space		4 Uses spoon and fork together, without help		4 Picture description: names 6+ objects in large picture	
5 Can stand and walk tip-toe 5+ steps		5 Knows own gender		5 Uses 2 or more descriptive words	
6 Walks upstairs: one foot on each step, adult manner		6 Plays well with other children		6 Tells well in sentences of 6+ syllables	
7 Can pedal a tricycle or other pedal toy		7 Can undo buttons		7 Names 18 objects in box	
8 Can cross both feet and both knees when seated		Can undress self		8 Names 6+ colours Tick if known: red, white, blue, orange, pink/lilac/purple, brown, green, yellow, grey, black	
9 Jumps off 2 steps		Washes own hands and face, with some assistance		9 Repeats one 6 syllable sentence	
10 Can walk a chalk or painted line at least 1.2m (4ft) long		10 Knows age		10 Comprehension (2+ items)	
Can run and kick a medium-sized ball		11 Can do up buttons		11 Defines by use (6+)	
12 Can jump over 15cm (6in) foam block hurdle		12 Gives family name		12 Uses 2+ personal pronouns correctly	
13 Walks downstairs, one foot on each step, adult manner		Can put on socks and shoes, unaided		13 Picture description: names 12 objects in large picture	
Can hop on one foot: 3+ hops		Can dress and undress self		14 Picture vocabulary (36+): INB: Administer after item FIX.10	
15 Can run fast out of doors		Manages topcoat, cardigan or raincoat unaided		15 Opposites (2)	
16 Touches toes, knees straight		Brushes own teeth, without assistance		16 Repeats one 10-syllable sentence	
17 Broad jump: 8" 5cm (15in) over foam blocks		17 Can fetch item in a shop on request		17 Picture description: one or more descriptive sentences	
18 Kangaroo jumps over 3 foam blocks		18 Can fasten shoe buckles		Materials (2+): 1. What is a table made of? 2. What is a window made of? 3. What is a house made of?	
SECTION III: A Total items = ___ x 2 =		SECTION III: B Total items = ___ x 2 =		SECTION III: C Total items = ___ x 2 =	

10 OBJECTS IN A BOX (Items C30.1, C30.7) Three out of correct order				PICTURE CARDS (Items C31.2, C31.14) Three out of correct order				DEFINES BY USE (Items C31.3, C31.11) Three out of correct order			
Chair	Cat	Brick	Watch	1. Ball	6. Spoon	11. Bird	16. Teapot/Kettle	1. Cup	4. Coat	7. Pencil	
Doll	Cup	Coin	Key	2. Shoe	7. Flower	12. Key	17. Flag	2. Knife	5. Car	8. Watch	
Ball	Spoon	Knife	Pencil	3. Dog	8. Horse	13. Umbrella	18. Shop	3. Chair	6. House	9. Key	
Horse	Button	Fork		4. Train	9. Cap/Hat	14. Hammer	19. Wheelbarrow				
Dog	Car	Plate		5. Boy	10. Bed	15. Cup	20. Owl				

TO EIGHTH YEARS

Subscale D Eye and Hand Co-ordination	Response	Subscale E Performance	Response	Subscale F Practical Reasoning	Response
1 Builds a tower of 8+ bricks		1 4-square board: 50 secs		1 Knows 'penny' or 'money'	
2 Copies a horizontal stroke		2 6-hole board: 50 secs		2 Repeats one digit (5, 6, 7)	
3 Handles scissors: tries to cut		3 Returns 9 bricks to box and puts lid on: 30 secs		3 Compares two insets for size	
4 Threads 4 beads		4 Reassembles screw toy		4 Repeats 2 digits (1-6, 5-9, 9-4)	
5 Copies a circle: Stage 1		5 4-square board: 40 secs		5 Knows 'big' and 'little'	
6 Folds a 10.2cm (4in) square in half		6 6-hole board: 40 secs		6 Preliminary counting to 4+	
7 Threads 11+ beads		7 Assembles brick boxes by colour: all 12 pieces		7 Compares two insets for height	
8 Copies a cross: Stage 1		8 11-hole board: 60 secs		8 Compares two lines for length	
9 Draws a person: Stage 1		9 Builds bridge with 3 bricks, inverted model		9 Can count 4 bricks correctly	
10 Scissors: can cut a square into two fairly equal halves		10 4-square board: 20 secs		Visual memory (3)	
11 Folds a 10.2cm (4in) square twice		11 Returns 9 bricks to box and puts lid on: 20 secs		11 Compares two weights	
12 Copies a letter: Stage 1		12 6-hole board: 20 secs		12 Knows right from wrong: 'Is it right or wrong to hurt someone?' 'Is it right or wrong to lie to someone?'	
13 Copies a square: Stage 1		13 Pattern making No. 2: 50 secs		13 Can count 10 bricks correctly	
14 Draws a house: Stage 1		14 Train under bridge successfully		14 Knows number of fingers on each hand	
15 Copies a circle: Stage 2		15 Pattern making No. 2: 40 secs		15 Can take out the middle brick	
16 Threads 11 beads to colour pattern		16 Pattern making No. 5: 50 secs		16 Repeats 4 digits (3-7-2-9, 5-8-1-6, 4-9-2-3)	
17 Copies 6+ letters		17 Builds 'gate' to model, using 3 boxes and lids		17 Can count 15 bricks correctly	
18 Scissors: can snip edge of paper		18 11-hole board: 40 secs		18 'Which costs more?' 'A bicycle or a ball?' (practice examples: 'A watch or an ice-cream?' (no. 1)	
SECTION III: D Total items = ___ x 2 =		SECTION III: E Total items = ___ x 2 =		SECTION III: F Total items = ___ x 2 =	

FORMBOARD	4-square	6-hole	11-hole
TRIAL 1	secs	secs	secs
TRIAL 2	secs	secs	secs

PATTERN MAKING	No. 2	No. 3	No. 4	No. 5
TRIAL 1	secs	secs	secs	secs

9 BRICKS TO BOX	
TRIAL 1	secs
TRIAL 2	secs

SECTION IV: THIRD TO EIGHTH YEARS

Subscale A Locomotor	Response	Subscale B Personal-Social	Response	Subscale C Language	Response
1 Can run upstairs		1 Has a special playmate		1 Comprehension (4+ items)	
2 Jump off 3 steps		2 Can get a drink of water from the tap or bottle, without assistance		2 Talks in sentences of 10+ syllables	
Can bounce and catch a tennis ball		Can wash and dry own hands and face, without any assistance		3 Names 10+ capital letters	
Hopscotch 1		Can choose own clothes		4 Similarities (1)	
5 Can jog at a steady pace all around playground		Can shampoo hair, with some assistance		5 Names 10 colours: red, white, blue, orange, pink/lilac/purple, brown, green, yellow, grey, black	
Can hopskip, recognisable		6 Knows address		6 Differences (2)	
7 Can jump over 25cm (10in) high stock hurdle		7 Can tie a single knot		7 Names 20+ capital letters	
8 Marches in time to tambourine		8 Eats without assistance		8 Similarities (2)	
Can throw a tennis ball up and catch it		9 Can lay a table completely, with some supervision		9 Differences (3)	
10 Runs downstairs		Can dress and undress completely, without help		10 Similarities (3)	
Hopscotch 2		11 Has one special school friend		11 Picture description: 3 descriptive sentences	
Can skip with a rope: 3+ single skips		12 Knows full address		12 Repeats one 16-syllable sentence	
13 Rides a bicycle (two-wheeler)		13 Knows birthday 1		13 Names 26 capital letters	
14 Static balance 2: can stand on one foot for 20+ seconds		Can tie a bow knot		14 Uses 4+ descriptive words	
Hopskips some distance in an open area		15 Can tie own shoelaces		15 Picture description: 4+ descriptive sentences	
Hopscotch 3		Can shampoo hair, without any assistance		16 Comprehension (6+ items)	
17 Rides a bicycle (two-wheeler) with skill		17 Can tie a double bow knot		17 Differences (4)	
18 Jumps off 4 steps		Baths or showers and dries self, without assistance		18 Uses 6+ personal pronouns correctly	
Fast skipping with rope: 12+ single skips		19 Can lay a table completely, without help or supervision, on all ordinary occasions		19 Differences (5)	
Skips well with rope: 12+ double skips		20 Knows birthday 2		20 Opposites (3)	
SECTION IV: A Total items = ×2 =		SECTION IV: B Total items = ×2 =		SECTION IV: C Total items = ×2 =	

Subscale D Eye and Hand Co-ordination	Response	Subscale E Performance	Response	Subscale F Practical Reasoning	Response
1 Copies 10+ letters		1 Pattern making No. 1: 40 secs		1 Knows number of fingers on both hands together	
2 Copies 6+ numbers		2 Pattern making No. 2: 50 secs		2 Can count backwards from 10	
3 Can write own first name		3 Returns 9 bricks to box and puts lid on: 20 secs		3 Knows morning and afternoon	
4 Copies a cross: Stage 2		4 Pattern making No. 4: 50 secs		4 'Which goes faster?' (3) 1. A dog dog running or a pussy 2. A bird flying or an aeroplane? 3. A car or a bicycle?	
5 Copies a triangle: Stage 1		5 Builds bridge with 3 bricks: superior model		5 Can say 6 of the 7 days of the week	
6 Draws a person: Stage 2		6 4-square board: 7 secs		6 'Which costs more?' 'A bicycle or a ball?' 'practice everyday' 'A cold drink or shoes?' (no. 3)	
7 Draws a house: Stage 2		7 Pattern making No. 3: 40 secs		7 Can count up to 30	
8 Copies 24+ letters		8 Pattern making No. 2: 25 secs		Picture arrangement 1: bird on road	
9 Copies a window: Stage 1		9 Pattern making No. 5: 30 secs		9 Knows right and left (6+): 1. Right hand 5. Left hand 2. Left ear 6. Right ear 3. Right foot 7. Left foot 4. Right eye 8. Left eye	
10 Copies a diamond: Stage 1		10 10-brick memory stairs		Picture arrangement 2: pouring a drink	
11 Copies 9 numbers		11 Pattern making No. 6: 40 secs		11 Knows 'long' and 'short'	
12 Copies a triangle: Stage 2		12 11-hole board: 30 secs		12 Days of the week (2+): 'What day comes after Tuesday?' 'What day comes before Saturday?' 'What day comes after Sunday?'	
13 Can write full name		13 Pattern making No. 7: 20 secs		13 Series	
14 Copies a square: Stage 2		14 6-hole board: 10 secs		14 Can count backwards from 20	
15 Copies a ladder: Stage 2		15 Pattern making No. 4: 30 secs		15 Knows 'heavy' and 'light'	
16 Copies a window: Stage 2		16 Returns 9 bricks to box and puts lid on: 15 secs		16 Knows 'high' and 'low'	
17 Copies a diamond: Stage 2		17 Pattern making No. 3: 25 secs		17 Repeats 3 digits (6-1-3,8-6, 5-9-2,7-3, 4-2-1-8-6)	
18 Draws a person: Stage 3		18 Pattern making No. 5: 20 secs		18 Repeats 3 digits backwards (7-4-6, 7-2-5, 4-9-8)	
19 Draws a house: Stage 3		19 Pattern making No. 4: 20 secs		Picture arrangement 3: building a house	
20 Credit as two items) (see Dif. 14 & Dif.5)		20 Pattern making No. 5: 10 secs		20 Directional arrows (4)	
SECTION IV: D Total items = ×2 =		SECTION IV: E Total items = ×2 =		SECTION IV: F Total items = ×2 =	

Subscale C

LARGE PICTURE

1. **Full verbatim report**: record everything the child says.

2. **Objects named** (nouns) N =
(Items CII.4, CII.13)

3. **Descriptive words used** (adjectives, adverbs) N =
(Items CII.5, CN14)

4. **Personal pronouns** and **possessive pronouns** N =
(Items CII.12, CN18)

5. **Descriptive sentences of 6 or more syllables** N =
(Items CII.17, CN11, CN15)

SPONTANEOUS SENTENCES

Item CII.6 6 or more syllables

Item CN2 10 or more syllables

REPETITION OF SENTENCES

Item CII.9 Repeats **8**-syllable sentences: one correct sentence scores as a pass
1. 'I have a little cat.'
2. 'My kitty caught a mouse.'
3. 'The mouse had a long tail.'

Item CII.16 Repeats **10**-syllable sentences: one correct sentence scores as a pass
1. 'My dog is a very good friend to me.'
2. 'I take my dog when I go for a walk.'

Item CN12 Repeats a sentence of **16** syllables: one correct sentence scores as a pass
1. 'It will be my birthday next week, Mummy will give me a party.'
2. 'The children were playing a game in the park and then they went home.'

COMPREHENSION
(Items CII.10, CN1, CN16)

1. 'What should you do if you feel tired?'

2. 'What should you do if you are cold?'

3. 'What is the thing to do if it is raining and you have to go out?'

4. 'What should you do if you are going somewhere and you missed the bus?'

5. 'What do you do if you feel lonely?'

6. 'What is the best thing to do if you are on your way to school, and you find it's getting late?'

7. 'What would you do if you were lost?'

OPPOSITES
(Items CN:15, CN:20)

1. 'A boy is big, a baby is.....?'
2. 'Coal is black, snow is.....?'
3. 'A lion is fierce, a lamb is.....?'

SIMILARITIES
(Items CN:4, CN:8, CN:10)

Practice example:
'You know the **moon** and the **stars**? Tell me how they are the same as each other. They are both...?'

1. 'How are a **bird** and an **aeroplane** the same?'
2. 'How are a **car** and a **bus** the same?'
3. 'How are a **door** and a **window** the same?'
4. 'How are a **pen** and a **pencil** (or **crayon**) the same?'

DIFFERENCES
(Items CN:6, CN:9, CN:17, CN:19)

Practice example:
'You know a **fly** and a **bee**? They are not alike, are they? They are not the same. How are they different?'

1. 'How are the **morning** and the **night** different?'
2. 'How are a **fish** and a **dog** different?'
3. 'How are **salt** and **sugar** different?'
4. 'How are a **triangle** and a **square** different?'
5. 'How are **winning** and **losing** different?'

Subscale D

Perpendicular stroke
(Item: DX:18)

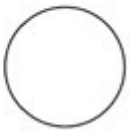
Young child's attempt at drawing
(Items: DX:21, DX:29, DX:30, DX:4, DX:9, DX:14)

Horizontal stroke
(Items: DX:19, DX:2)

GRIFFITHS MENTAL DEVELOPMENT SCALES – EXTENDED REVISED (GMDS-ER)

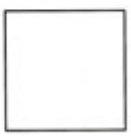
SUBSCALE D: DRAWING BOOK

Name of child: ..... Date of assessment: .....



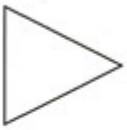
Copy a circle
(Items: DX:5, DX:15)

Copy a cross
(Items: DX:6, DX:6)



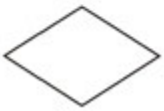
Copy a square
(Items: DX:13, DX:14)

Copy a ladder
(Items: DX:12, DX:15)



Copy a triangle
(Items: DX:5, DX:12)

Copy a window
(Items: DX:9, DX:16)



Copy a diamond
(Items: DX:10, DX:17)

Draw a person

Draw a house

(Items DN1, DN8)

A B C D E F G

H I J K L M

N O P Q R S

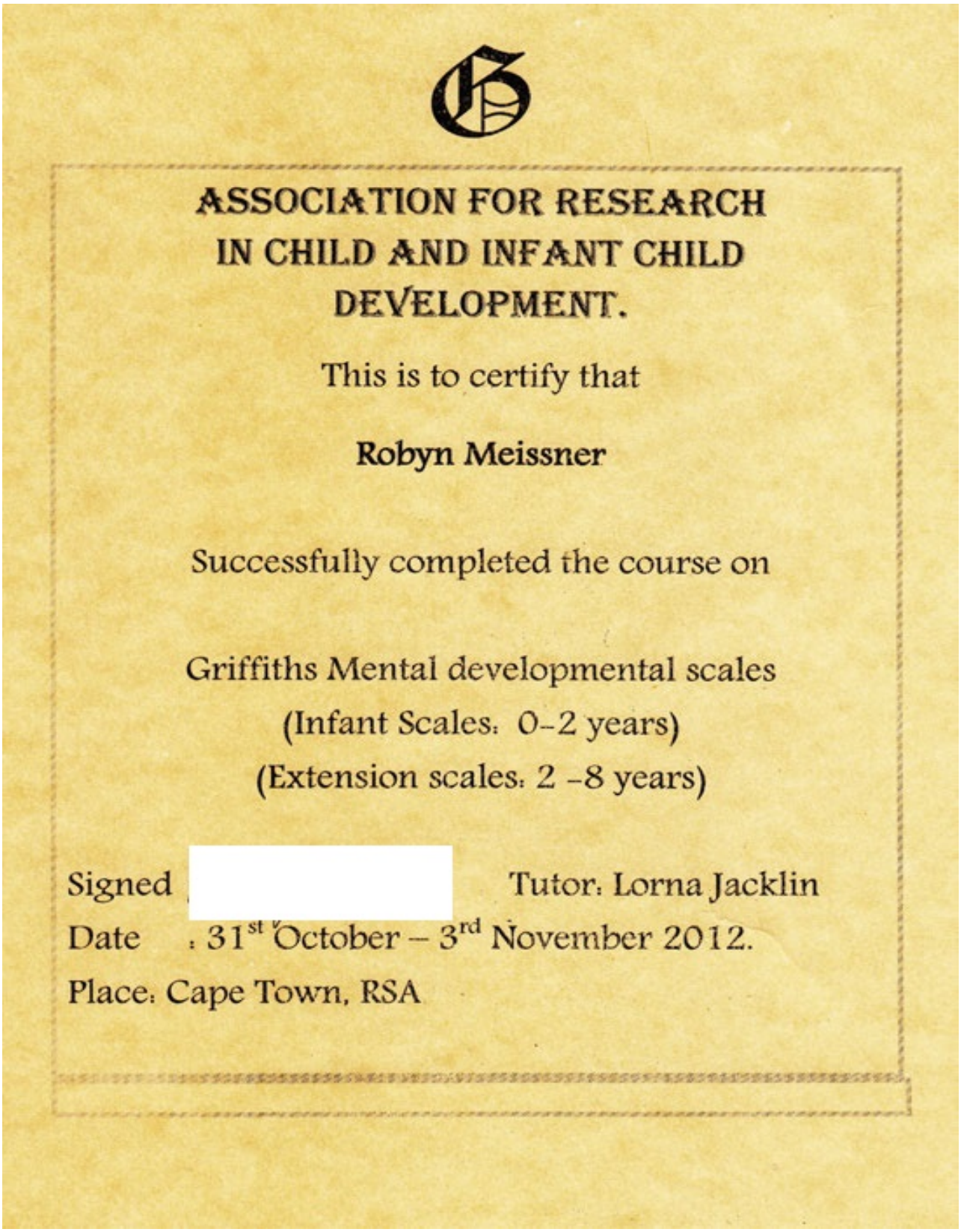
T U V W X Y Z

(Items DN2, DN11)

1 2 3 4 5 6 7 8 9

Write full name (Items DN3, DN13)

Appendix G: GMDS certificate



ASSOCIATION FOR RESEARCH IN CHILD AND INFANT CHILD DEVELOPMENT.

This is to certify that

Robyn Meissner

Successfully completed the course on

Griffiths Mental developmental scales
(Infant Scales: 0-2 years)
(Extension scales: 2 -8 years)

Signed [redacted] Tutor: Lorna Jacklin

Date : 31st October – 3rd November 2012.

Place: Cape Town, RSA

Appendix H: WeeFIM Score Sheet

WeeFIM

Score Sheet

Participant number:

DOB:

Date of test:

Age:

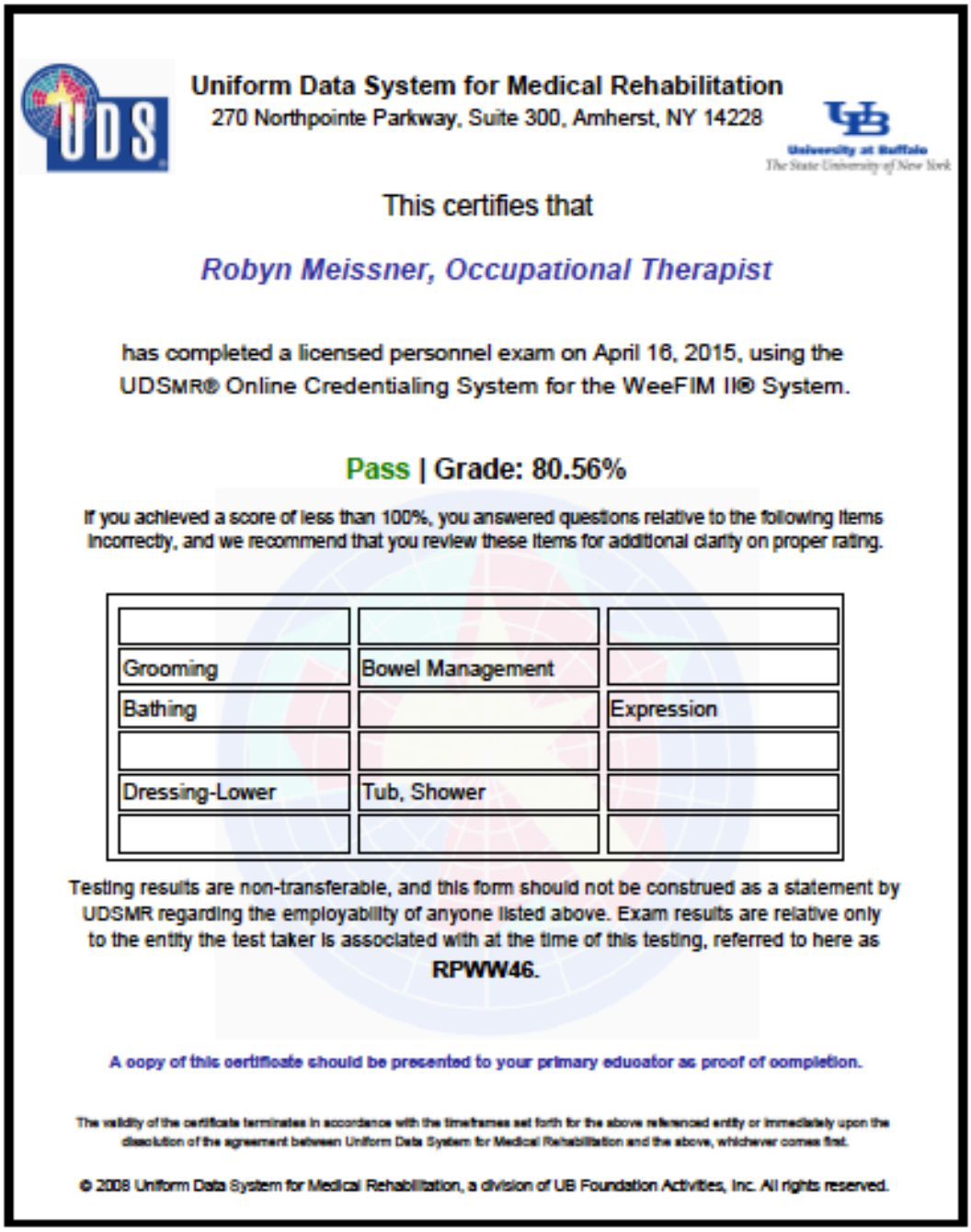
Assessor:

- ☐ Baseline Ax
- ☐ Mid Ax
- ☐ Post Ax

Area	Score	Reason	Observed or Reported
SELF CARE			
1. Eating			☐ Observed ☐ Reported
2. Grooming			☐ Observed ☐ Reported
3. Bathing			☐ Observed ☐ Reported
4. Dressing: Upper			☐ Observed ☐ Reported
5. Dressing: Lower			☐ Observed ☐ Reported
6. Toileting			☐ Observed ☐ Reported
7. Bladder management: level of assistance			☐ Observed ☐ Reported
8. Bladder management: frequency of accidents			☐ Observed ☐ Reported
9. Bowel management: level of assistance			☐ Observed ☐ Reported
10. Bowel management: frequency of accidents			☐ Observed ☐ Reported
Self Care Total			
MOBILITY			
11. Transfers:			☐ Observed

chair/wheelchair			◻ Reported
12. Transfers: toilet			◻ Observed ◻ Reported
13. Transfers: bath/shower			◻ Observed ◻ Reported
14. Locomotion: walk/wheelchair/crawl			◻ Observed ◻ Reported
15. Locomotion: stairs			◻ Observed ◻ Reported
Mobility Total			
COGNITION			
Communication			
16. Comprehension			◻ Observed ◻ Reported
17. Expression			◻ Observed ◻ Reported
Social Cognition			
18. Social interaction			◻ Observed ◻ Reported
19. Problem solving			◻ Observed ◻ Reported
20. Memory			◻ Observed ◻ Reported
Cognition Total			
WeeFIM Total			

Appendix I: WeeFIM credentials



Uniform Data System for Medical Rehabilitation
270 Northpointe Parkway, Suite 300, Amherst, NY 14228

University at Buffalo
The State University of New York

This certifies that

Robyn Meissner, Occupational Therapist

has completed a licensed personnel exam on April 16, 2015, using the UDSMR® Online Credentialing System for the WeeFIM II® System.

Pass | Grade: 80.56%

If you achieved a score of less than 100%, you answered questions relative to the following items incorrectly, and we recommend that you review these items for additional clarity on proper rating.

Grooming	Bowel Management	
Bathing		Expression
Dressing-Lower	Tub, Shower	

Testing results are non-transferable, and this form should not be construed as a statement by UDSMR regarding the employability of anyone listed above. Exam results are relative only to the entity the test taker is associated with at the time of this testing, referred to here as **RPWW46.**

A copy of this certificate should be presented to your primary educator as proof of completion.

The validity of the certificate terminates in accordance with the timeframes set forth for the above referenced entity or immediately upon the dissolution of the agreement between Uniform Data System for Medical Rehabilitation and the above, whichever comes first.

Appendix J: Information letter

Information letter to caregivers for participation in pilot study

School of Health and Rehabilitation Sciences

Faculty of Health Sciences

Divisions of Communications Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

F45 Old Main Building, Groote Schuur Hospital,

Observatory 7925

Dear parent/caregiver

Thank you for taking the time to read this information letter. My name is ... and I am an occupational therapist (OT) busy doing research with other researchers, to find out how to improve development for children living with HIV.

We have found that many of our children attending our ARV clinics are developing and learning slowly and/or struggling at school. Therefore, we are researching what are effective ways to improve development, play and learning for children living with HIV.

Before the main study can begin, one of the tests used to evaluate treatment needs to be checked to see if two different people can get the same results if they are testing the same child. This is important to make sure that the results collected during the main study are accurate.

I would like to invite you and your child to participate in checking the test. The test assesses movement, interaction, language, eye-hand coordination and ability to recognise shapes and numbers, and takes 2 hours to administer. Four researchers will watch your child perform a number of tasks that are required as part of the test, but write what they see separately. The information they collect will be used to check if they are able to observe the same level of performance in your child.

The assessment will be carried out at Victoria Hospital, in the OT Department where you usually bring your child for follow-up treatment. The researchers will find out from you about suitable time convenient for you. You will be provided with funds to cover the cost of using public transport. You will receive this on the day of the assessment.

You are under no pressure to participate in this study and you have the right to withdraw at any point without providing an explanation. There will be no penalty involved should you wish to withdraw. The researchers or the hospital cannot use your decision to refuse participation or withdraw against you in any way.

There are no risks in taking part in the study and there will not be any reward. The information collected in checking the test will however be used as part of the treatment you are already receiving from your OT.

Thank you for considering this request. Please find the consent form attached for you to complete. Ethics approval has been obtained from the Faculty of Health Sciences Human Research Ethics Committee of the University of Cape Town (HREC Reference number 560/2013).

Please forward any question or concern you may have regarding this research to the contact details furnished below. You may contact the HREC if you have any concerns regarding your and your child's rights or welfare as research participants.

Researcher:

Robyn Meissner (robyn.jess@gmail.com)

Jessica Ferguson (ferguson.jes@gmail.com)

Caraleigh Otto (caraleigh@nthandohome.co.za)

Anande Uys (anandeuys@gmail.com)

Cell: 0737150749

Principal Investigator:

A/Prof Professor Elelwani Ramugondo

Elelwani.Ramugondo@uct.ac.za

021- 406 6048

Chairperson of the UCT faculty of Health Sciences Human Research Ethics Committee (HREC):

Professor Marc Blockman

021- 406 6496

Information letter to caregivers for participation in main research study

School of Health and Rehabilitation Sciences

Faculty of Health Sciences

Divisions of Communications Sciences and Disorders, Nursing and Midwifery, Occupational Therapy, Physiotherapy

F45 Old Main Building, Groote Schuur Hospital,

Observatory 7925

Tel: +27 (0) 21 406 6401 Fax: +27 (0) 21 406

Dear parent/caregiver

Thank you for taking the time to read this information letter. My name is ... and I am an occupational therapist (OT) busy doing research with other researchers.

We have found that many of our children attending our ARV clinics are developing and learning slowly and/or struggling at school. Therefore, we are researching what are effective ways to improve development, play and learning for children living with HIV.

We are researching two different types of therapy. A computer program will randomly allocate all participants to only one of the two therapies so unfortunately you or your child will not be able to choose which intervention you and your child will be part of.

One intervention involves individual therapy where your child would be seen by an occupational therapist for an hour, working on your child's specific needs. The other intervention involves 1,5 hour group sessions for caregivers and their children facilitated by an occupational therapist. These groups will assist caregivers to know how to stimulate their children at home. Both of these interventions will take place once a month at Groote Schuur Hospital with 10 sessions in total. Therefore, a monthly commitment will be required from you and your child to be able to attend most of the sessions.

To be able to see whether our intervention is effective we will need to assess the children and require you to fill in some forms. We need to assess the children before, during and after the intervention to record progress. Assessments will be approximately 2,5 hours and needs to be completed at 5 to 6 month intervals. For the assessments your child will be required to complete certain activities for example, building blocks, running or drawing. Your child will also be video recorded on how they naturally play in the Groote Schuur playroom. The researcher will be the only one who will look at this video and then destroy the video afterwards. You will also be required to fill in forms regarding general details about your family and how you feel about parenting. Your assessments and details will be kept strictly confidential.

At some point during the study, you and your child will be provided with a 'GO box' (a take home toolkit) in which various materials such as balls, crayons, and toys will be provided for you to use with your child at home. Assessments and interventions will be carried out at Groote Schuur Hospital, at the pediatric out-patient clinic where you bring your child for follow-up treatment. The researchers will find out from you about suitable time convenient for you and your child. You will be provided with R20 to help cover the cost of using public transport. You will receive this on the day of each visit.

You and your child are under no pressure to participate in this study and you and your child have the right to withdraw at any point without providing an explanation. There will be no penalty involved should you and your child wish to withdraw. The researchers or the hospital cannot use your decision to refuse participation or withdraw against you or your child in any way.

There are no risks in taking part in the study and there will not be any reward. Findings from the study will be analyzed by the research team and used for presentations, reports and research publications. No identifiable information about you or your child will be collected at any point during the study.

Thank you for considering this request. Please find the consent form attached for you to complete. Ethics approval has been obtained from the Faculty of Health Sciences Human Research Ethics Committee of the University of Cape Town (HREC Reference number 560/2013).

Please forward any question or concern you may have regarding this research to the contact details furnished below. You may contact the HREC if you have any concerns regarding your and your child's rights or welfare as research participants.

Researcher's details:

Robyn Meissner (robyn.jess@gmail.com)

Jessica Ferguson (ferguson.jes@gmail.com)

Caraleigh Otto (caraleigh@nthandohome.co.za)

Anande Uys (anandeuys@gmail.com)

Cell: 0737150749

Principal Investigator:

A/Prof Professor Elelwani Ramugondo

Elelwani.Ramugondo@uct.ac.za

021- 406 6048

Chairperson of the UCT faculty of Health Sciences Human Research Ethics Committee (HREC):

Professor Marc Blockman

021- 406 6496

Appendix K: Consent form

Consent forms for caregivers to participate in the pilot study

Title: A pilot study to determine the inter-rater reliability on the Griffiths Mental Development Scales – Revised & Extended Revised (GMDS – R & ER)

I, ……have read (or had read to me by ……) the Information Sheet. I understand what is required of me and my child. I do / do not consent to both our participation in the study (Circle appropriate response). All my questions have been answered. I do not feel that my child or I are being forced to partake in this study. I choose to participate of my own free will. I am aware that I can withdraw from the study at any time should I wish to do so. I have been assured that if I refuse to participate in the study or choose to withdraw at a later stage there will be no consequences for me or my child.

Signed:…… Date: ……

Caregiver Full Name:……

Place:……

Researcher:……Signed:……

Witness:.....
Signed:.....

Consent forms for caregivers to participate in the main research study

Consent form to participate in study titled: The effects of play-informed care-giver implemented home-based intervention on participation outcomes for HIV positive children on HAART and living in families with low socio-economic status.

I, ……. (caregiver's name) have received the information sheet from …….. (researcher's name) about the research study. I understand what is required of me and my child to participate in the study.

The following has been explained to me:

☐ The purpose of the research study

☐ The two types of intervention: Group and individual therapy

☐ Monthly commitment for intervention

☐ R20 to assist with transport

☐ Assessment to record progress before, during and after intervention

☐ Video assessment

☐ Box of toys at some time during the next 12 to 14 months

☐ Confidentiality

☐ No pressure or obligation to be part of the study

☐ I can withdraw at any stage without negative consequences

All my questions have been answered. I do not feel that my child or I are being forced to partake in this study. I choose to participate of my own free will. I am aware that I can withdraw from the study at any time should I wish to do so. I have been assured that if I refuse to participate in the study or choose to withdraw at a later stage there will be no consequences for me or my child.

Tick your chosen response:

☐I do consent to both our participation in the study (you agree).

☐I do NOT consent to both our participation in the study (you disagree).

☐ I do consent to the video assessment

☐ I do NOT consent to the video assessment

Signed:…… Date: ……

Caregiver Full Name:……

Place:……

Researcher:……Signed:……

Witness:.....

Signed:.....

If child's legal guardian is not the caregiver:

☐I do consent to my child's participation in the study (you agree) with the above caregiver.

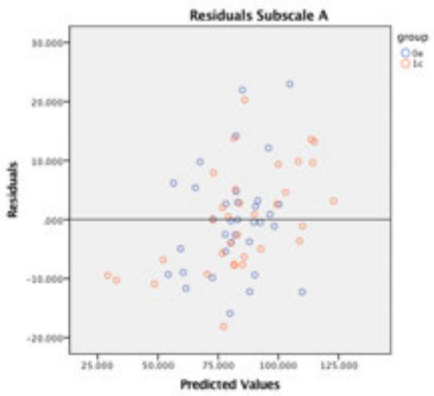
☐I do NOT consent to my child's participation in the study (you disagree).

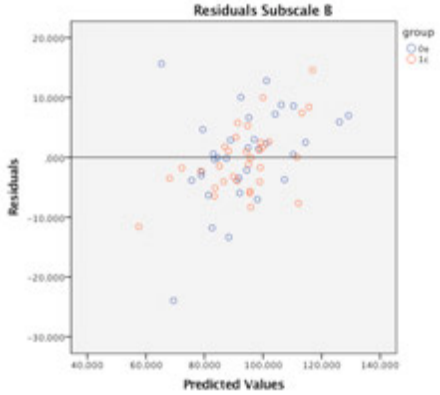
Signature of guardian:.....

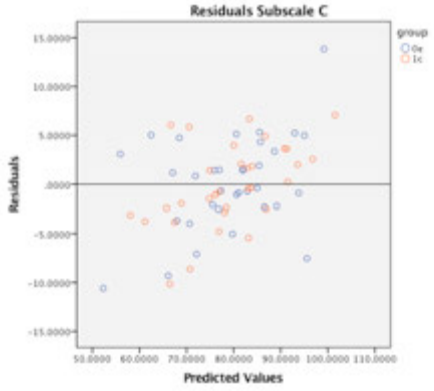
Date:.....

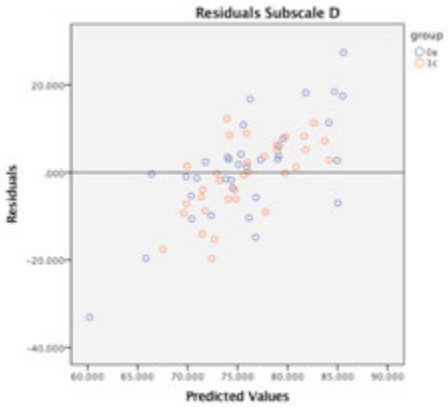
Guardian Full Name:.....

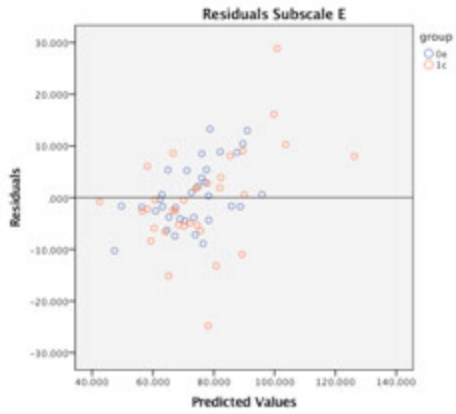
Appendix L: Mixed model diagnostics

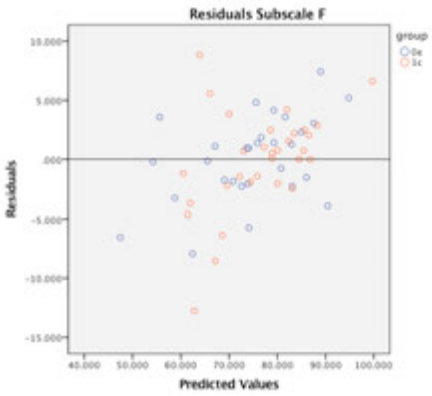


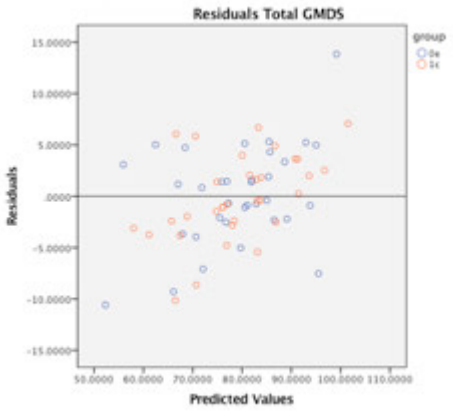








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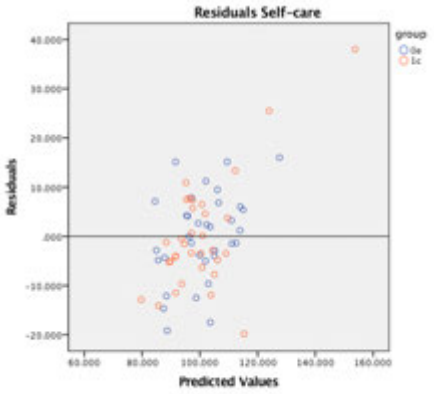
1c
Residuals
Predicted Values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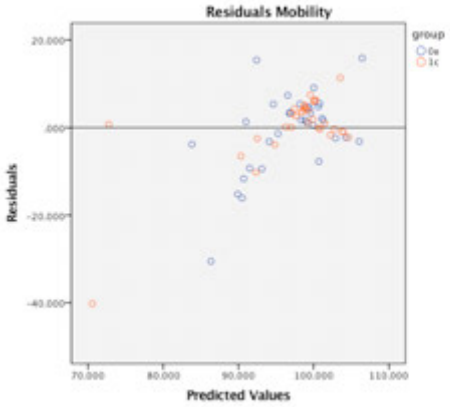
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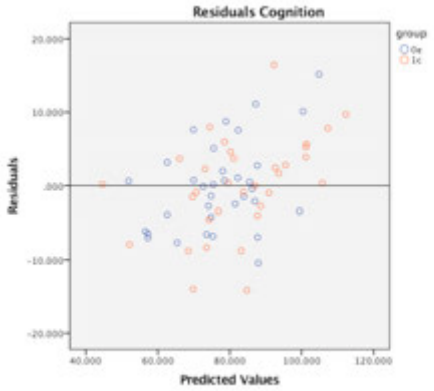
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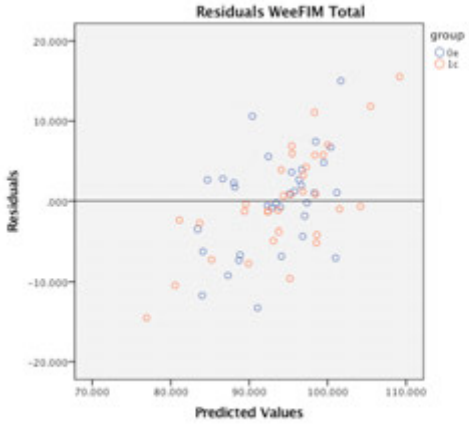
Predicted Values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Residuals
Predicted Values

Appendix M: Constructs in GMDS subscales

The table gives more details to what constructs are assessed the items in each subscale. Ticks in red are listed in the manual (ARICD, 2006).

Constructs	Subscale A Locomotor	Subscale B Personal-social	Subscale C Language	Subscale D Eye-hand coord.	Subscale E Performance	Subscale F Practical reasoning
Power and strength	✔					
Agility and flexibility	✔					
Depth perception	✔			✔	✔	
Body coordination	✔	✔		✔	✔	
Visual-motor integration	✔	✔		✔	✔	
Balance	✔					
Self concept		✔				
Interpersonal skills		✔				
ADL independence		✔				
Receptive language		✔	✔			✔
Basic concept knowledge			✔			✔
General knowledge			✔			✔
Memory			✔		✔	✔
Reasoning			✔			✔
Expressive language		✔	✔			✔

Form and size perception				✔	✔	✔
Creativity				✔		
Visual-spatial reasoning					✔	
Sequential reasoning						✔

Appendix N: Superiority sample size calculation

Based on demonstrated evidence for the effectiveness of a basic home stimulation programme on the development of young children infected with HIV (Potterton et al, 2010), which was also conducted in a low-resourced context in South Africa – the anticipated difference was estimated at an improvement of 8-10 points on the GMDS/GMDS-ER General Quotient score in the experimental group and an improvement of 2-4 points in the control group.

If all children in the population were to be recruited (N=72, n=36 per group), a power of 88% will be achieved at a superiority difference of 6 between groups with a standard deviation of 8. If 15% of the population were lost to follow-up, this power would be 82.8%

Retrospective power of a sample size of 14 in each group equalled 47.2% power.

Appendix O: Example of a PICIHBI session

Session 1 of Toddler group (0-2years old)

SESSION 1

Skill Focus: GROSS MOTOR CO-ORDINATION

Session Focus:
Introduction to program and theme of "Active Bodies, Healthy Children"

Session Goal:
To introduce GOKidz program and encouraging gross motor activity in the child and highlight its link to overall development

GO BOX items: box, beanbag, bubbles, CG flip file, Session 1 CG handout

Other items: LEGO; bucket; appointment cards; register, pens, star chart and star stickers, general toys for play and motivation.

1. Welcome

- Welcome caregivers
- Register taken
- Tea/coffee
- ***Welcome everyone to your first GO KIDZ group. My name is ..... I am an occupational therapist or you can say OT. OT's help children to develop and learn so that they can improve their body and mind skills so that they can reach their full potential. However these groups are here to help YOU, the caregiver, help your child at home and it's not about me being the main person to help your child. You are the one who spends time with the child, knows the child best and can make a real difference so I want to help you be the special person to help your child. Therefore the responsibility lies with you to gain the skills you learn here and apply them at home with your child.***
- Introduce group co-facilitator: ***This is ... (assistant) who will help to translate and assist me in the groups.***
- Introduce childminder: ... ***(childminder) is the childminder who will look after the children during the first part of the session.***
- Group member introductions: ***We will talk more about what is involved in these group sessions in a little while but first I would like everyone else to introduce themselves. Please can you can also tell us the name of your child, age and something that tells us a little more about who your child is for example what is their personality, or something that she enjoys doing. Second round going in a different order: please tell us something that you hope for your child's future.*** Relate CGs responses of their hopes and dreams for their children to how the group can benefit them and provide a stepping stone to help their children to get there. Also relate how they know their children best and they are the best ones to help their children and thus we, the facilitators are supporting them to do this.

2. Introductory activities

WALL DEMONSTRATION

Therapist explains that CG's are going to imagine that they are building a wall representing their child's life. The wall bricks (LEGO) are in the facilitator's box. Each brick in the wall represents a skill that the child learns as they grow and development. Start building the wall. Ask CGs to think back to what they child was learning to do as an infant and what they are currently doing. Examples: roll, sit, stand, walk; babble; words; talk etc. Discuss how there was a progression of development in their children e.g. first sit then stand etc. Point to some of the lower bricks to show that those bricks could represent some of the earlier skills.

Questions and discussion points while building:

- ***What has your child learnt to do up to this stage? What others things can your child do?*** Use examples provided to build the wall.
- Skills are built from the bottom up not from the top down. Therefore the easier skills are established first. Explain that sometimes we pressure our kids with something too difficult before they have established the foundational basic skills. (refer to a faulty wall being built as a result as this builds gaps in wall where splinter skills develop)
- Explain foundation for success and our aim to build 'full, strong walls' in our children's lives to give the greatest potential for future success. Refer to later academic, career and life success.
- Poke some gaps in the wall. Explain that sometimes holes in the wall or gaps in the child's development occur. Even though the children might seem as though they are "fine" there could be gaps and the child might actually have weaknesses in the foundations. See how the man still sits on top of the wall despite that there are gaps in the foundation but a little pressure and the wall will fall.
- Gaps. Ask CGs what could cause these gaps (illness, defaulting ARV's, missing school, being in hospital, having no one to help at home, ill caregiver, death/change of caregiver, lack of attention and no opportunities to play etc.). Explain how gaps can affects their future success in occupations - poor skill development results in poor schooling results in poor success in future.
- Our aim is to build strong walls and fill any gaps that are present and prevent any gaps in the future.
- All bricks/skills are important – the child needs all the skills.
- See how they are all connected and overlap
- ***Who/what are the builders?*** (incorporate why this intervention) – ***Who is the primary builder in your child's life?***
- Age range of when milestones should be reached
- Aiming for children to become ready for school so that they have the skills in place to cope with the challenges at school. Skills needed for academic subjects such as mathematics and literacy do not just start at school but start from when the child is young.

EXPLAIN THE PROGRAM

Explain the various points of how the groups will run:

- Sessions are once a month and correspond with clinic appointments days at *time.
- The session is structured so that the first half of the session involves the CGs only and second half includes both CGs and their children.

- Remember that you are signing up for YOU and your child – this is for you – you need to come (try not to swap CGs). The sessions build on each other.
- The Session topics include: (Session topics are repeated so there are 10 sessions in total)
    - Gross Motor skills
    - Discovery and experimentation, preconstruction and learning
    - Fine Motor skills
    - Language and literacy
    - Self care and independence
    - Discipline
- You can wait in the waiting area before the session starts
- If you miss a session or cannot make it please phone the number inside your file and leave a message or "please call me". *Therapist to ensure number is inside caregivers file*
- We take the register each session to note how frequently people attend and to see if you qualify for an attendance certificate at the end of the program – you need to attend at least (6) out of the 10 sessions to qualify for a certificate. The certificate only shows your commitment to the program and does not provide you with a qualification. *Therapist to determine number of sessions for certificate. The alternative option is to give certificates to everyone but to write on the certificate how many sessions have been attended. Certificates can also be given out half way through the program after session 5.*
- The children also put a star on their star chart each time you attend a session (show star charts).
- Please try your best to be on time. We also keep track of if you come on time or late so that we know if you have missed information in the group. Unfortunately, you are also missing an opportunity to learn and understand things fully if you come late as you might miss something important. Being on time also helps us to respect each other.
- It might be a good idea to plan to arrive 15 min before session starts.
- Remember this is NOT MY group but OUR group so please get involved as much as you can – ask questions, participate, take responsibility of tasks etc. Do not think of me as the master of everything – we all learn from each other. We all have different experiences and knowledge which we can share so that we learn from each other. I also like to ask lots of questions to hear your thoughts – I am not trying to test you at all but I would like to know what you think and learn from you. You might also have an opportunity to participate in the group by asking one of you to take the register for a session.
- If you miss a group session please do not expect to get all the items from the previous session. You can't miss all the sessions and then come to the last session and expect to get all the items in the box.
- Attending the sessions is your choice and your commitment. These sessions could provide you and your child a great opportunity to develop.
- Please try do nappy changes and toileting before or after session if possible.
- For this age group, if child has to be with the CG then it will be alright but preferably they would stay in the play room for the first part of the session.
- Part of the program you receive a box. This is a box for you and your child. Some sessions, you will also receive some items to put in the box so that you can play with the items at home with your child. Some sessions you might receive many items and some sessions you might not receive an item. These items need to be looked after eg they should not be taken by others and go to neighbours etc. If an item is lost or broken we cannot replace it. Please bring the box and the items to every session as we might use them again in a future session and we might add more items to the box.

3. The skill - Gross Motor Co-ordination

Relate to the skills discussed in wall demonstration that make up GMC.

Explain what GMC is or otherwise known as: Gross motor skills/physical activity/body, movement and coordination skills.

- GMC is the ability to perform big body movements with smoothly To perform gross motor movements well you need good posture and strong muscles (especially stomach and back muscles), good balance; move well within the space around you; use both sides of the body and work on both sides of your body by turning "rotating" your body. Ask CGs how a little toddler walks compared to an 8 year old. They can demonstrate to make it fun. Ask why these two children walk differently. Discuss how big body movements become refined as balance and coordination improves. Explain how this helps older children to participate in more advanced activities.
- GMC provides a foundation for more advanced skills
- Development of a toddler's body and movement skills provide the postural control and foundation necessary to gain advanced physical skills including small controlled movement needed for tasks such as drawing and writing and using the hands in a controlled manner (skills necessary for development and success at school in the future). This is because controlled and coordinated large gross motor movements must be in place before smaller movements can be refined. If you think of 2 lemon trees - one with a thin weak trunk and another with a strong thick trunk – the tree with the thin trunk will not be strong enough to support large branches and fruit whereas the stronger trunk will be able to produce many branches and a lot of large lemons. A child's gross motor skills and core strength is like the trunk of the tree and the child's fine motor skills such as using the hands are the branches and the lemons could be activities such as drawing – so the better the child's gross motor activities the better they will be able to use their hands and the better they can perform activities like drawing.
- Children who struggle with big body movements may also struggle with:
    - limited to participate in activities and games e.g. running games or games using both hands together
    - Low self-esteem and confidence in big body movements used in play. Discuss confidence and independence that is developed in play.

4. Activities and ways to build the skill

Note: there are many additional activities that could be encouraged but just a few have been given as there is lots to discuss in the first session and we do not want to overwhelm the caregiver. Use your discretion according to the child and caregiver needs as to any additional activities you want to suggest.

GIVE OUT BOX WITH ITEMS AND CG FILE WITH SESSION HANDOUT Go though and do the activities (briefly with the CGs before the children join (to facilitate playfulness in CGs). Teach the songs to CGs beforehand.

- **General Tips:**

Integrate activities into everyday routine

Make activities/tasks fun and playful.

Facilitate movement: Demonstrate and help moms facilitate transitional movements *(demonstrate what these are)* by encouraging the child to move from one position to another by themselves. Do not just place them in a position. For example, do not lift the child from sitting into standing – help them to learn what the movement feels like to move from sitting to standing naturally. Remember to encourage rotation in the trunk. Facilitate movement for rolling, 4-point kneeling; crawling; pulling up to stand; standing; cruising; walking.

Tummy time for babies: Spending time on her belly helps your baby to develop coordination between her upper and lower body. This will assist in her muscle and movement development. Give your baby toys to play with in this position and she can lift up supporting herself with her arms.

Animal walks: Pretend with your child that you are wild animals crawling through the jungle. Examples of animals can include lion, elephant, giraffe, snake, bunny, frog, bird, dog etc or think of your own. They can also crawl up and down inclines and over obstacles such as over pillows and chairs using your imagination. The caregiver can also explain what the animal is like to the older toddler.

- **Beanbag Activities. INTRODUCE BEANBAG**

Throw, catch, and aim at goals or targets. This can be done from different positions: sitting, kneeling, standing etc. The child can also catch the beanbag with a bucket/container.

> *Therapist's note: In session show how to grade activities in terms of distance, speed, direction, catching against chest etc. Show how to help child put hands together to help catch. Give ideas of targets (eg boxes, containers, poster on the wall) and skittles (plastic bottles, empty cans, etc) that can be used. Explain age group typically likes to throw things and this is part of their play and development (they are not being naughty). CGs should encourage throwing with appropriate items in a safe context. Explain benefits of child also running after beanbag and picking beanbag up.

Balancing act: Balance beanbag on child's head. Child can try balance the beanbag on their head standing still and to make it more difficult they can try walk with the beanbag balancing on their head.

> *Therapist's note: Explain grading - They can start walking slow and when they get better they can walk faster and turn around and move around obstacles.

- **Bubble activities INTRODUCE BUBBLES**

Child catches bubbles with one and/or two hands. Child can also clap the bubbles or stomp the bubbles with their feet. You can also let the child run and chase after the bubbles. They can also try catch the bubbles with the bubble wand. You can also let the child try and blow the bubbles.

> *Therapist's note: explain blowing bubbles helps to also encourage oral motor skills

Chase games: pretend to chase your child then have the child chase you

> *Therapist's note: explain grading by using sharp turns to upgrade.

Dance together: Move and dance to music with your child. If your baby is not yet walking you can dance with your baby in your arms or your child can bob up and down and move their arms and legs to the music

in a sitting position. Babies like to sway, roll, bounce, clap, stretch, waltz, glide or turn. Encourage your toddler to use her body and move freely to any type of music.

*Therapist's note: Encourage CG to describe the details of the child's actions as he dances to the music. "Look how you are bouncing your body to the beat. I see how you like to bob your head up and down when you dance." This not only helps him learn new words but also instils a sense of pride that his actions are noticed! Children this age often do not change their movements to match the music, but rather will respond to their own internal rhythm. CGs are to encourage children to move regardless whether it relates to the music or not.

- **Everyday tasks and tips**
  - Let the child Pick up items from the floor and throw/put in container and tidy up
  - Get child to fetch items you ask him or her to fetch
  - Let the child get to places by himself as much as he can (i.e. avoid constantly picking him up and putting him somewhere – he must get there himself). Let the child crawl/walk/climb where they need to.
  - Let the child do things for himself
  - To encourage sitting for the child that is still learning to sit independently, prop child up in sitting position against your body or in box with pillows

5. Experiential application with the children

*Therapist's note: coach individual CGs with children not yet sitting and crawling and briefly some support tips to facilitate these skills

INTRODUCTION:

Children come in and sit with/next to CGs in a circle on the floor. Open with welcome song (Example: Track 1 of Xhosa Fundis, see below). You will need to teach the caregivers the song.

Welcome song words:	Actions:
Molo Mama (hello mother)	Wave to mamas
Molo Tata (hello father)	Wave to tatas (if none just wave)
Molo Sisi (hello girl)	Wave to girls
Molo Bhuti (hello boy)	wave to boys
Molo Sana (hello baby)	wave to all children
Molo Sana (hello baby)	wave to all children
Sana lwam (my baby)	
Kunjani?	

ACTIVITY 1: ANIMAL KINGDOM

Use animal walks. Give one or two examples and then ask caregivers what animals and walks they can think of. Examples of animals that can be used: dog, cat, mouse, frog, worm; other animals such as lion,

elephant, giraffe might not be known to child. Bring in element of playfulness of pretend play and explain benefits of this play eg using imagination & creativity, abstract thinking, playfulness. Still encourage basic pretend play with infants as a way of playful interaction even if the child might not understand fully, it gives the CG an opportunity to be playful, using different expressions and voices/sounds. Encourage CGs to use animals that the child knows. Children not yet crawling can be animals in prone/puppy. Benefits of tummy time and lifting head can be discussed. Caregivers with younger infants that are not crawling/walking might work on facilitating movements during this time. To upgrade – child can move over obstacles and do move advanced movements with animals e.g. running, jumping and hopping.

ACTIVITY 2: BEAN BAG

The caregiver can play with the bean bag. The caregiver can first come up with their own activities to do with the beanbag. Other suggestions include throw and catch (therapist to help with grading and facilitation); aiming at targets eg bottle (older children); throwing in a bucket (or their box); putting bean bag in and out of box/bucket; putting on head; walking with bean bag on the head.

ACTIVITY 3: BUBBLES

The child tries to pop the bubbles while caregiver blows bubbles..

Popping variants:

- Child swipes with one hand
- Child pops bubble with pointed finger
- Child pops bubble by clapping
- Child pops bubble by kicking/stomping with foot

Although blowing bubbles comes into another session, the child might want to blow the bubbles themselves which is alright. This can be an opportunity to start learning turn taking for the toddler eg child blows and then caregiver blows then child blows etc.

6. Closure

CGs and children pack away activity items in box. Give a quick summary of key learning points. Encourage CGs to follow through with activities often. Star put on star chart. Remind of next group date and give out appointment card. Sing good-bye song (example below).

Good-bye song words:	**Actions:**
Good-bye everyone,	Clap as you sing
Thank you for today.	
We wish you peace,	
We wish you hope,	
As you go your way.	

Word Count

Total word count: 29 220

Excluding reference list: 25 701